

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK: PART 48

IN RE: OPIOID LITIGATION

INDEX NO.: 400000/2017

August 17, 2020
Central Islip, New York

MINUTES OF FRYE HEARING
(Testimony of Dr. Kessler)
& Mr. James Rafalski

B E F O R E: HON. JERRY GARGUILO
Supreme Court Justice

A P P E A R A N C E S:

SIMMONS HANLY CONROY, LLC
Attorneys for Suffolk County
112 Madison Avenue
New York, New York 10016
BY: PAUL J. HANLY, JR., ESQ.
JAYNE CONROY, ESQ,
(212) 784-6401
phanly@simmonsfirm.com
jconroy@simmonsfirm.com

NAPOLI SHKOLNIK, PLLC
Attorneys for Nassau County
400 Broadhollow Road, Suite 305
Melville, New York 11747
BY: HUNTER SKOLNICK, ESQ.
SALVATORE C. BADALA, ESQ.
JOSEPH L. CIACCIO, ESQ.
(212) 397-1000
pnapoli@napolilaw.com
sbadala@napolilaw.com
jciaccio@napolilaw.com

LETITIA JAMES

Attorney General for the State of New York

Office of the New York State Attorney General

28 Liberty Street

New York, New York 10005

BY: MICHAEL REISMAN, ESQ.

SEEGER WEISS, LLP

Attorneys for Plaintiffs

77 Water Street, 8th Floor

New York, New York 10005

BY: PARVIN K. AMINOLROAYA, ESQ.

(212)584-0700

O'MELVENY & MYERS, LLP

Attorneys for Janssen Pharmaceuticals, Inc.

1625 Eye Street NW

Washington, DC 20006

BY: STEPHEN D. BRODY, ESQ.

(202)383-5300

sbrody@omm.com

O'MELVENY & MEYERS, LLP

Attorneys for Janssen Pharmaceuticals, Inc.

7 Times Square

New York, New York 10036

BY: NATE ASHER, ESQ.

JONES DAY

Attorneys for Walmart, Inc.

250 Vesey Street

New York, New York 10281

BY: STEPHANIE H. JONES, ESQ.

SHARYL A. REISMAN, ESQ.

(212) 326-3939

shjones@jonesday.com

sareisman@jonesday.com

KIRKLAND & ELLIS, LLP
Attorneys for Allergan Finance, LLC,
F/K/A Actavis, Inc.,
F/K/A Watson Pharmaceuticals, Inc.
655 Fifteenth Street, NW
Washington, DC 20005
BY: JENNIFER G. LEVY, ESQ.
(202)879-5000
jennifer.levy@kirkland.com

COVINGTON & BURLING, LLP
Attorneys for McKesson Corp. and
PSS World Medical, Inc.
The New York Times Building
620 Eighth Avenue
New York, New York 10018
BY: Paul W. Schmidt, ESQ.
(212)841-1000
pschmidt@cov.com

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STEPHANIE CASAGRANDE, CSR, RPR
OFFICIAL COURT REPORTER

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THE COURT OFFICER: All rise.

THE CLERK: Supreme Court, State of New York, County of Suffolk, New York State Opioid Litigation, Part 48 is now in session, the Honorable Jerry Garguilo presiding.

THE COURT: Good morning, everybody. Welcome back. Please be seated.

THE CLERK: This is a continued hearing In Re Opioid Litigation, Index Number 400000 of 2017.

THE COURT: Okay. Do you want appearances?

THE CLERK: Counsel, your appearances.

MR. SHKOLNIK: Hunter Shkolnik, on behalf of Nassau County. Good morning, your Honor.

THE COURT: Good morning.

MR. BADALA: Good morning, your Honor. Salvatore Badala, on behalf of Nassau County.

THE COURT: Good morning.

MR. CIACCIO: Good morning, your Honor. Joseph Ciaccio, on behalf of Nassau County.

THE COURT: Good morning.

MR. ASHER: Good morning, your Honor.

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2 Nate Asher, for defendant Janssen.

3 THE COURT: Good morning.

4 MS. CONROY: Good morning. Jayne

5 Conroy, plaintiff.

6 MS. AMINOLROAYA: Good morning, your

7 Honor. Parvin Aminolroaya, from Seeger

8 Weiss, for the plaintiff.

9 THE COURT: Good morning. Anyone else?

10 Okay.

11 MR. REISMAN: Good morning, your Honor.

12 This is Michael Reisman from the New York

13 State Attorney General's office for the State

14 of New York.

15 THE COURT: Good morning, sir. I'm

16 sorry, something else?

17 MR. BRODY: Good morning, your Honor,

18 Steve Brody for the Janssen Defendants.

19 THE COURT: Good morning. Anyone else?

20 MS. LEVY: Good morning, your Honor.

21 Jennifer Levy is here for the Allergan

22 Defendants.

23 THE COURT: Good morning, Ms. Levy.

24 MR. SCHMIDT: Good morning, your Honor.

25 Paul Schmidt, for McKesson. I may ask

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2 questions with the next witness. I will ask
3 questions with the witness.

4 THE COURT: Good morning.

5 DR. KESSLER: Good morning.

6 THE COURT: I'll count to five before I
7 -- remind the witness, please.

8 THE CLERK: Dr. Kessler, I'll remind you
9 you're still under oath.

10 THE WITNESS: Thank you.

11 THE CLERK: You can be seated.

12 THE COURT: Doctor, have a seat.

13 THE WITNESS: Thank you, your Honor.

14 THE COURT: Doctor, you recall the
15 pointers I gave you last week, correct?

16 THE WITNESS: Yes, sir.

17 THE COURT: Very good. So I won't
18 repeat them. You may continue.

19 MR. BRODY: Thank you, your Honor.

20 CONTINUED CROSS-EXAMINATION

21 BY MR. BRODY:

22 Q. Good morning, Dr. Kessler.

23 A Good morning, Mr. Brody.

24 Q. Dr. Kessler, with the benefit of the
25 weekend to streamline things, I think I have the

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remainder of this down to 45 minutes or less. So there will be no issue with you making your 1 p.m. phone call today.

A Many thanks, Mr. Brody.

Q. I want to come back to sort of your starting point on what you described as your methodology. And in this case, you're offering your opinion that certain marketing by opioid manufacturers violated FDA regulations or departed from industry standards, right?

A The latter, yes. I don't want to get overly legal on violated, but yes, deviations.

Q. Okay. Now --

MR. BRODY: I think that we have somebody who is not muted, your Honor. All right. That's better.

BY MR. BRODY:

Q. Dr. Kessler, can you still hear me?

A I can, sir.

Q. Now, FDA regulations contain terms of art; don't they?

A I think that would be fair.

Q. Now, substantial evidence, that's a term that you referenced in your testimony on Friday

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under questioning from Mr. Shkolnik, right?

A Correct.

Q. Now, I think as you explained it, FDA wants claims about benefits of medications to be supported by substantial evidence as defined in the regulations, right?

A Correct.

Q. And, in fact, substantial evidence is a defined term; isn't it?

A It's defined for effectiveness, yes.

Q. Yeah, and although I think you would say there has been a lot of discussion about it, substantial evidence typically needs two adequate and well-controlled clinical investigations, right?

A That's fair. It says adequate and well-controlled clinical investigations. There's an S on that, and that has generally been interpreted more than once, for more than one.

Q. Exactly. Now, you understand what an open-label study is; don't you?

A Yes.

Q. And an open-label study, just so that we're on the same page, is one where researchers and participants both know which treatment the patient

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is receiving, right?

A Yes. It's actually used in a number of different contexts. Sometimes people are, are loose with it, but it just -- that's one interpretation, yes.

Q. It can be used to compare different treatments?

A Tell me what the "it" is.

Q. An open-label study.

A Well, if it's an open-label study, then it can't be, because it's not adequate and well controlled. So I'm not sure I'm getting your question.

Q. Well, let me ask it this way.

Open-label study results appear in peer-reviewed journals; don't they?

A A lot of things, yes. I mean, I'm sure they can, yes.

Q. But you would agree that an open-label study, as we have defined it, would not meet FDA's requirements for an adequate and well-controlled clinical investigation, correct?

A Unless there's extenuating circumstances, perhaps. Certain studies would be

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2 impossible to do open label, I guess, is what I'm
3 saying.

4 Q. So, Dr. Kessler, you recall giving a
5 deposition in this case, correct?

6 A I do.

7 Q. And if we can bring up, it's page 48 of
8 that deposition on 7 through 11, and you were asked:
9 An open-label study measuring effectiveness would
10 generally not meet FDA's requirements for an
11 adequate and well-controlled study, correct?

12 And you answered: Fair.

13 That was your testimony, right?

14 A Yes.

15 Q. Now, putting aside the idea of an
16 open-label study, we could have a situation where
17 all real world experience supports a promotional
18 statement, but there are no well-controlled clinical
19 investigations and FDA would say that is not
20 substantial evidence in its eyes, right?

21 A You'd have to give me a little more so I
22 understood it exactly. You have to give a little
23 more facts so I fully understood, but I think
24 generally I would agree with your point.

25 Q. Right. So generally -- well, let's take

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1 a situation where there are no well-controlled
2 clinical investigations, but all real world
3 experience supports a statement, the FDA could still
4 say, you know what, you don't have your two adequate
5 and well-controlled clinical investigations to
6 support this statement.
7

8 So, you know, the DDMAC arm that you
9 talked about could then say, well, you know what, we
10 believe that's false and misleading, right?

11 FDA could say that's not substantial
12 evidence in its eyes?

13 A Again, I think it's a little more
14 nuanced than that.

15 Q. Doctor, could we go back to the
16 deposition testimony you gave.

17 A Sure.

18 Q. If we could pull up page 54 on 15 to 25.

19 And, Doctor, you were asked: Let's take
20 a situation where there are no well-controlled
21 clinical investigations, but all real world
22 experience supports the statement. FDA could still
23 say, you know what, you don't have your two adequate
24 and well-controlled clinical investigations to
25 support this statement. And so, you know, we,

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2 DDEMAC and OPDP, believe that's false and
3 misleading.

4 And your answer was: FDA could say that
5 is not substantial evidence in its eyes.

6 Right?

7 A FDA could say that, correct.

8 Q. Now, for the benefit of the Court, OPDP
9 is the Office of Prescription Drug Promotion, right?

10 A Correct. The subsequent naming of
11 DDEMAC.

12 Q. Right. And you, in your testimony on
13 Friday, referred to DDEMAC. DDEMAC is now known as
14 OPDP, right?

15 A Correct, fair.

16 Q. Every time a manufacturer creates a
17 promotional piece for a medication, a branded
18 promotional piece for a medication, the manufacturer
19 is required, before it starts using that promotional
20 piece, to provide that promotional piece to FDA with
21 what is known as a Form 2253, correct?

22 A Certainly prior to launch that
23 requirement is accepted, yes.

24 Q. And, again, prior to use, even post
25 launch, prior to use of a promotional piece, the

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1 manufacturer sends a copy of it with a 2253. Now,
2 of course, the manufacturer doesn't have to wait for
3 FDA to get back to it, but it does have to submit
4 it, correct?

5
6 A I'd have to go back and look at the
7 regs, but to your line in every promotional piece
8 has to be submitted, I don't see every promotional
9 piece submitted.

10 Q. Well, let's not get tripped up on that.
11 Let's, let's go back to the situation that we were
12 just talking about where we have all real world
13 experience supporting one thing, but we don't have
14 your two adequate and well-controlled clinical
15 investigations, that situation where you acknowledge
16 FDA can say that is not substantial evidence in its
17 eyes, FDA might then send the manufacturer that made
18 the promotional statement a warning letter or an
19 untitled letter for a regulatory violation, right?

20 A In your hypothetical you left undefined
21 all world -- every -- all world experience. I mean,
22 I get your point, Mr. Brody. FDA could, if there's
23 not substantial evidence, send a letter, certainly.

24 Q. Company sends a warning letter, correct?

25 A Well, you know, it depends on what

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points in time FDA's history and what its basis was for a warning letter over an untitled letter.

Q. Right, exactly. And that letter would use as boilerplate the term false and misleading to describe that promotional statement that was consistent with all real world experience, right?

A Yeah. I don't -- I won't agree with -- excuse me. I don't want to quibble, but the term boilerplate seems to trivialize.

When FDA sends a letter, there's a concern on the part of the agency. It's usually not just a trivial concern or some bureaucratic concern. It's concerned because patients could be at risk.

Q. So, Doctor, boilerplate is actually your term; isn't it?

A I've certainly used the word boilerplate, no question.

Q. Yeah. And, in fact, if we can go -- you, in fact, have used the word boilerplate to refer to FDA's designation as a statement that violates its regulations as false and misleading; haven't you?

A You'd have to show me exactly what I've said. I've talked about the last lines in a letter,

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1 if that's what you're referring to, but, you know, I
2 don't have a perfect recollection exactly how I
3 phrased it.
4

5 Q. All right. Let's take a look at your
6 deposition from this case. Recall page 55, lines 1
7 through 12. And as to this hypothetical situation
8 that we have been talking about, you were asked:

9 FDA would then use the term, as it does
10 in warning letters, the term false or misleading to
11 describe the promotional communication, correct?

12 You said: If there's usually
13 boilerplate sentences that you could look to any of
14 those letters and you would see that it would be
15 probably violative under section so and so, you were
16 asked, right, and you would use the term false and
17 misleading, correct, and you agreed or whatever
18 relevancy there was. Yes.

19 Do you recall giving that testimony?

20 A I gave exactly that testimony.

21 Q. All right. Now, you, in this case, are
22 not giving any opinion on how the term false and
23 misleading, when used by FDA, compares to any
24 standard that the Court should imply in this case to
25 evaluate the Plaintiffs' claims; are you?

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A You're correct. I was giving no legal opinion, and I think I said in my deposition, sir, but I left it to the Court to -- and to the lawyers to discuss relevance of any FDA violations.

Q. All right. Let's -- and just so we're clear, let's turn to another example of the point we have been discussing.

You offered -- well, on Friday I asked you about the Mallinckrodt medication Exalgo; do you recall that?

A Correct.

Q. And you offered the opinion in your expert report in this case, you pointed to the fact that Mallinckrodt was highlighting the physiochemical properties of Exalgo, namely, that it is difficult to crush, and if crushed, it -- and exposed it to water, it forms large particles or I guess the exact word is agglomerates, correct?

A I think that that may be discussed in my report. I don't remember that from Friday. Maybe I'm misremembering.

Q. We talked generally about Exalgo. We did not get to this point, which is why I want to get to this point now.

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2 A I'm happy to discuss it. Any specific
3 points on agglomeration and Mallinckrodt, I'd love
4 to pull my notes to refresh my memory, but I'm happy
5 to answer your questions.

6 Q. Well, let me ask you this question
7 first: You understand that one of the ways that
8 opioid pills have been abused is when users crush
9 them and then snort or dissolve and inject them,
10 right?

11 A That's fair.

12 Q. And so if a pill is difficult to crush,
13 it's harder to abuse that way, right?

14 A Generally.

15 Q. Same if particles agglomerate when
16 they're exposed to water, it's harder to dissolve in
17 water to the point where the drug can be injected,
18 right?

19 A I would leave that to a physical
20 scientist to answer.

21 Q. Although you -- and this was -- if you
22 want to take a look at it, this was paragraph 523 of
23 your expert report, but my question is: Although
24 you highlighted and seem to criticize Mallinckrodt
25 for its statements about Exalgo, you have no

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evidence to suggest that it would not be difficult to crush the pill; do you?

A Again, if I can, if I can pull my notes, I could refresh my memory on that specific circumstance so I can see exactly what I've said.

Q. Well, why don't we, why don't we -- Doctor, if you could --

A I just want to get my notes so I can -- on that, if that's okay, counselor.

Q. That's fine, Doctor, but my question was a little different. My question was: Although you criticize Mallinckrodt for its statements about Exalgo, you have no evidence to suggest that it would not be difficult to crush the pill; do you?

A I'd have to review exactly what I criticized in order to be able to answer that. I'd need a minute.

MR. BRODY: Ms. Radford, can we bring up Dr. Kessler's deposition, page 189.

MR. SHKOLNIK: Your Honor --

MR. BRODY: Lines 5 through 11.

MR. SHKOLNIK: The doctor was still trying to answer the prior question, was looking at his notes.

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BY MR. BRODY:

Q. Dr. Kessler, do you recall -- you were asked in your deposition --

THE COURT: Mr. Brody, Mr. Shkolnik essentially raised an objection.

You're saying there's an incomplete answer. You want the witness to complete the answer?

MR. SHKOLNIK: Yes. He was looking at his notes. Thank you.

THE COURT: That's fine. Mr. Brody, as we move on -- Mr. Shkolnik, you also, of course -- this is a Frye hearing.

And if one were to use buzz words in connection with the elements of a Frye hearing in terms of the testimony, one would expect, in connection with a contested expert, you used the phrase general acceptance, reliability, and in some instances consensus. That comes from, I believe, Judge Kaye's concurring opinion.

I appreciate where you're going, but it sounds to the Court like your questions are more expected perhaps at a trial in terms of

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foundational questions, and if I'm wrong
you'll tell me, and you're going to tell me,
Judge, I'm going to connect this up, I'll let
you do that.

MR. BRODY: Your Honor, I am going to
connect it up.

THE COURT: That's enough. Just say
subject to connection. Go ahead.

MR. BRODY: Sure.

BY MR. BRODY:

Q. Dr. Kessler, is there anything you
needed to add in response to the question I asked
you?

A Right. I mean, so, again, I need to
look at my exact opinion, but I believe -- well,
with regard to the hard outer shell, I think
Mallinckrodt acknowledges that they could make no
claims concerning that potential, right? That's my
recollection. And the issue is could they make
claims without them having that.

I think that's what the record shows,
but I may be mistaken, and I may have to review
that, Mr. Brody.

MR. BRODY: So, Ms. Radford, can we

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bring up page 189, lines 5 through 11,
please.

BY MR. BRODY:

Q. And, Doctor, you were asked in your deposition: What evidence do you have to suggest that it would not be difficult to crush an Exalgo tablet?

And you said: I'm not making -- I have no such evidence. I did not seek independent evidence of that, just that it was not proved there was not -- and here we see this term of art again -- substantial evidence to support that claim.

That was your testimony, right?

A That was exactly my testimony.

Q. Right. And what you meant, in fact, was that the crush-resistant claim in your view didn't meet the FDA's substantial evidence definition under the standards, correct?

A I apologize. I can't remember exactly what I meant at the time, but what would be logical that I meant is that Mallinckrodt itself had said that they were not in possession of such evidence and recognized in the record that it could not make that claim.

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So I'm a little confused, Mr. Brody, on why you're asking me whether I made an independent, because that was not my -- that was not the basis of my opinion. It was that Mallinckrodt didn't have evidence and acknowledged that.

Q. In fact, Doctor, you are saying that there is not substantial evidence, in FDA parlance, that it's difficult to crush an Exalgo tablet, correct?

A I'm not sure I'm saying I am -- well, I'd have to review the record exactly, if you can show me exactly what I said to be exact, but, in fact, if Mallinckrodt didn't have that evidence and was aware that they didn't have that evidence and yet -- and stated they didn't have that evidence and went ahead and made that claim, then there was not substantial evidence. So I'm not sure we're differing or not, Mr. Brody.

MR. BRODY: Ms. Radford, could you bring up page 189, line 12 through page 190 -- actually, 12 -- let's go 12 through 18, 189.

BY MR. BRODY:

Q. And, Doctor, you were asked: You're not stating the claim that it's difficult to crush an

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Exalgo tablet is false; are you?

And you answered: What I'm saying is there is not substantial evidence of that.

Correct?

A I said exactly that, sir.

Q. And when you answered the question that way, you were using the definition of substantial evidence that's the FDA's definition, the agency's definition, correct?

A Sure.

Q. All right. And as to agglomeration, you are not offering the opinion that it is untrue that when crushed, Exalgo results in large particles; are you?

A Same answer as earlier. I would leave that to a physical chemist. I am looking at the record on what Mallinckrodt had about agglomeration. So I'm not giving an independent judgment, you're correct, on agglomeration.

I'm basing it on what the record of what Mallinckrodt had as substantial evidence.

Q. So the answer is you're not offering the opinion that it is untrue that when crushed, Exalgo results in large particles? You're not saying that,

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correct?

A I am not saying that. What I am saying is that Mallinckrodt said, quote, while we can make no claims concerning abuse potential, physicians may be interested and started talking about agglomeration. That's what I testified.

So they were aware they couldn't make any claims.

Q. So you are not saying that when crushed and exposed to water, Exalgo does not agglomerate? You're not offering any opinion on that, correct?

A No. I'm telling you on the record, that based on the record that Mallinckrodt had stated that it could not make any claims with regard to abuse potential with regard to agglomeration.

That's what I'm saying. I'm not, I'm not the physical chemist to talk about agglomeration.

Q. And you're saying they couldn't say it based on the FDA's substantial evidence standard, correct?

A No. I mean -- well, maybe, perhaps. I'd have to look exactly. What I'm saying is just very simply, looking at Mallinckrodt documents that

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say we can't make any claims about the abuse potential so -- and yet I went ahead and made those claims. So that's my only point here.

MR. BRODY: Ms. Radford, can we bring up page 189, line 20 to page 190, line 1.

BY MR. BRODY:

Q. And when you were explaining this in your deposition, you were asked whether you were saying by substantial evidence, you're using the definition of substantial evidence that you used earlier with me when I was questioning you, you said: I think that's -- generally we would stay within the agency's definition.

That was your testimony, right?

A I've only had one definition of substantial evidence, and it's the same as the FDA's definition.

Q. And, in any event, you didn't go out and ask any New York doctor who prescribed Exalgo whether they held any view on whether it was difficult to crush; did you?

A I -- again, I stayed with the record. I didn't do anything separate from the record.

Q. So is that a correct -- I'm correct,

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right? You didn't go out and ask any New York doctors who prescribed Exalgo whether they had any view on whether it was difficult to crush; did you?

A No. I relied on the surveys and studies in general that the companies did. I didn't do independent surveys.

Q. Now, Doctor, I want to shift gears here a little bit and ask you a couple of questions about some things that you didn't talk about on Friday.

You know what a pill mill is, right?

A Sure.

Q. You know, often times we, you know, and I think we've all read stories about pill mills where doctors have had patients, you know, lined up outside, midnight, one in the morning, handing over cash for things like OxyContin prescriptions, right?

A You and I, I think, agree. I'm not sure it's midnight, one a.m. Perhaps we've all seen pictures on the evening news, et cetera, on that, and I'm familiar and have read about such behavior.

Q. You, in this case, you made no effort to quantify the extent to which prescriptions from pill mills led to opioid use disorder in the State of New York; did you?

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A Not in those terms, no.

Q. And you made no effort to quantify the extent to which prescriptions from pill mills led to overdoses in the State of New York; did you?

A Specifically, no.

Q. Same answer for illegal drug sales, right?

A I mean, I guess in that narrow sense, you're correct, Mr. Brody.

Q. And you made no effort to quantify how the extent of opioid use disorder from prescriptions that were handed out by pill mills might compare to opioid use disorder in New York patients who received legitimate prescriptions for one of the Defendant manufacturers' medications; did you?

A I made some effort on a portion of that question, but not the way you phrased it.

Q. You didn't make any effort to quantify that? I mean, if you did, I apologize. I missed it. I didn't see it in your report.

A No, no, no. I did not, I did not make any quantification of pill mills per se. You're correct. I mean, or illegal use, per se, beyond the scope.

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Q. All right. So one of the things you did talk about on Friday was the illicit drug trade; you recall that, correct?

A Sure.

Q. And I believe the way you put it when you were talking on Friday was you referred to waves of the opioid abuse crisis; am I recalling that correctly?

A Fair. I used that term. CDC used that term. So I used that, yes.

Q. All right. And you referenced heroin use and the illicit -- I believe the illicit drug trade, right?

A That was generally -- heroin was usually viewed as the second wave I believe.

Q. Right. Now, in this case, you have not made an effort to determine the extent to which the illicit drug trade in New York has led to opioid use disorder, correct, to quantify that?

A A little more -- I mean, I think that's probably fair, but, again, more complicated because you'd have to go -- I mean, there is data -- I think we've probably talked about it -- of the prescription drug use, you know, in about 80 percent

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triggers that illicit use.

So just state your question again.

Q. My question is a little different.

You made no effort to determine the extent to which the illicit drug trade in New York led to opioid abuse disorder, did you, to quantify that?

A That is correct. I dealt with an earlier stage of prescription drug use and certainly can comment about how prescription drug use impacted illicit, but I know there's other witnesses that will do that.

Q. Right. And so you didn't make any effort to determine, to quantify the extent to which the illicit drug trade in New York led to opioid overdoses; did you?

A That's correct. My other experts will. I focused on prescriptions and prescription's effects on illicit use.

Q. You made no efforts to determine the extent to which -- by the way, do you know what diversion is?

A Sure.

Q. And diversion can take different forms.

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2 Diversion can be something where somebody gets a
3 prescription for a medication, for an opioid
4 medication, they don't take all of it, they sell the
5 rest on the street or they leave it in a medicine
6 cabinet and it gets taken by somebody who it's not
7 prescribed for. There's all sorts of different
8 forms that diversion can take, right?

9 A Fair, Mr. Brody. When you asked me
10 whether I knew what diversion was, I would have
11 footnoted that and said many people have different
12 definitions.

13 Q. You made -- one thing we can agree on, I
14 think, is you made no efforts to quantify the extent
15 to which diversion led to opioid use disorder in the
16 State of New York; did you?

17 A No. But just -- no. You'd have to go
18 back the step. Everything my report deals with how
19 prescription drugs fueled --

20 Q. Well --

21 A -- correct.

22 Q. So same answer for overdoses or illegal
23 drug sales, right, connected to diversion?

24 A Prescription --

25 MR. SHKOLNIK: Objection to the form,

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your Honor.

THE COURT: Doctor, just say -- Doctor,
there's an objection.

MR. BRODY: I can rephrase.

THE COURT: Rephrase the question.

BY MR. BRODY:

Q. You did not conduct any analysis to
quantify the extent to which diversion led to
overdoses or illegal drug sales in the State of New
York; did you?

A Correct. Other experts will testify on
that.

Q. All right. I want to focus on something
else that --

MR. BRODY: Actually, before we go on
there, Ms. Radford, do we still have the
demonstrative that we started on Friday?

THE COURT: Okay.

MR. BRODY: So let's knock off analyze
the impact of pill mills illicit drugs for
diversion. We'll cross that out.

Thank you, Ms. Radford.

BY MR. BRODY:

Q. And we will come back to this one more

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time before we finish today, Dr. Kessler, but before we get there, when you were answering questions on Friday from Mr. Shkolnik, you indicated that you looked back at the way doctors prescribed opioids before 1990; do you recall that?

A I certainly looked at the history, yes.

Q. One of the things you didn't talk about on Friday was the history of the way the federal government has looked at the issue of chronic pain; did you?

A And the use of opioids?

Q. Correct.

A I think I've looked at that, but, again, you know, I mean, there's always a large history. I may not have looked at everything.

Q. Are you familiar, Doctor, with the Interagency Committee on New Therapies For Pain and Discomfort?

A The late '70s, if I'm correct.

Q. That would be the one, yes.

A And stipulated by the White House Czar Peter Bourne?

Q. That is right. Are you familiar with it?

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A Under President Carter.

Q. Yes, sir.

A It's an interesting part of our history, right?

Q. It was. And as part of that history, you understand that the White House pushed for the establishment of the Interagency Committee on New Therapies For Pain and Discomfort, right?

A Dr. Bourne did as the drug czar.

Q. And that interagency committee prepared a report; didn't it;

A Recommendations, yes, sir.

Q. Yeah. Why don't we take a look at that.

MR. BRODY: Ms. Radford, this is Tab 11, if we can bring that up.

BY MR. BRODY:

Q. And, Dr. Kessler, I think you can see it on the screen there, right?

A I can see it.

Q. Right. If we go to page 12, Ms. Radford, you will see a list of the members of the committee. Maybe we can make that a little bigger so we all can see it.

It includes doctors from numerous parts

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of the Department of Health Education and Welfare
now known as HHS, right?

A Yes. It was stimulated by Seymour
Perry. You left his name off, I think, historically
he was the head of -- right above that. Yes, you're
correct.

Q. Right. Actually, on the next page,
Ms. Radford, we'll see that the National Institute
on Drug Abuse and the National Institute of Mental
Health on the following page was included, along
with numerous officials from FDA, including the
chief of the drug abuse staff of the Division of
Neuropharmacological Drug Products, right?

A Yes, Stuart Nightingale, who worked for
me, is on there.

Q. Right. Now, if we turn ahead to page 50
and we pull this out, Ms. Radford, just at the top
there so we can see it a little better.

The committee held a consensus
development conference program on pain, discomfort
and humanitarian care in 1979; didn't they?

A Yes. This was all focused on terminal
care, I believe.

Q. Well, you know, let's take a look at

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that. If we go to page 57, and what we see is -- go down a little further to the presentation by Dr. Bonica, Ms. Radford.

We see that Dr. Bonica, on the first day of the conference, opened the discussion with a general overview of chronic pain as a serious national health problem, right?

A Sure.

Q. And described the magnitude of disabling chronic pain through statistics advising that about 75 million Americans were suffering from some kind of chronic pain and that their disabilities resulted in a loss of approximately 700 million work days every year, correct?

A That's exactly what he says.

Q. The interagency committee built on this meeting and other information to offer its view of what it called the current status of pain therapy. And if we can go ahead, Ms. Radford, to page 180 of the document, and I believe you're correct that part of the focus of the interagency committee was on terminal care.

A I think the -- I don't think it was just -- I'm sorry. Is there a question?

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Q. Sure. Part of it was on terminal care --

A No. I think the major thrust -- sorry.

Q. I'm sorry. You need to let me finish my question.

Part of the focus was on terminal care, part of the focus was on cancer pain, and part of the focus was on chronic pain more broadly, correct?

A My memory of this, this was a focus on use of heroin, et cetera, in terminal cancer pain. That's my memory. The gravamen of this whole thing was on terminal illness.

Q. Well, let's take a look and let's take a look at the current status of pain therapy.

There's a section here called Chronic Pain. And what the committee observed was that chronic pain, defined as pain which persists or recurs at intervals for months and years, is caused not only by chronic pathologic processes in the body or nervous system, but also by psychopathology and environmental influences, right?

A That's what that page says.

Q. And they observed that many patients with chronic pain undergo progressive physical

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deterioration, develop anxiety, depression and other emotional disturbances; didn't they?

A Yes.

Q. And they go on to say that chronic pain can lead people to become estranged from their families, lose their jobs and even commit suicide, correct?

A That's what that says, sure.

Q. And although they indicated that the effects were especially severe in patients with cancer pain, their focus was not so limited.

A I think the report is limited, is focused on terminal illness if you go back to the beginning of the document. I mean, you have to refresh my memory here, sir.

I mean, I know you're on page 111, but if you go to the beginning pages of this document, I believe this is about terminal illness, and that's really what it was addressing.

Q. Well, let me ask you this, Doctor, since you said that we would need to refresh your recollection on this, this is not -- I believe this is not on the list of materials that were provided to us as materials you considered in arriving at the

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expert opinions that you're offering in this case;
am I wrong about that?

A No. I mean, I did not specifically cite
this document. I cited other documents that showed
that opioids were used prior to 1990 primarily in
cancer pain. This is not inconsistent with that.

Q. So one of the other government documents
that I want to take a look at is -- and this one I'm
sure you're familiar with and probably more familiar
with this one than with the interagency committee
report, and that is a report from the CDC that came
out just two years ago.

MR. BRODY: Ms. Radford, can we go to

Tab 12.

BY MR. BRODY:

Q. And, Doctor, you are familiar with the
Centers for Disease Control's morbidity and
mortality weekly report, correct?

A Yes, an MMWR?

Q. Correct. I assume you're familiar with
this report, prevalence -- which includes a
discussion of the prevalence of chronic pain and
high impact chronic pain among adults in the United
States in 2016, correct?

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A Yes. This is one of a whole host of CDC documents it had issued during the epidemic.

MR. BRODY: And if we go to page 5, CDC on page 5 defines -- and, Ms. Radford, maybe we can just go to the definitional sections at the very bottom in the notes section of the table there. I'm sorry. The bottom of the table, just -- I think you have it highlighted. There you go. Yeah, right there. That's perfect.

BY MR. BRODY:

Q. CDC defines chronic pain as pain on most days or everyday in the past six months. And then below that is a definition for high impact chronic pain, which we see chronic pain limiting life or work activities on most days or everyday in the past six months; do you see that?

A Fair, yes. Good definition.

MR. BRODY: And if we flip back to page 3, we see a summary of the findings in this MMWR. And actually, Ms. Radford, if we can go to the highlighted portion -- perfect.

BY MR. BRODY:

Q. In 2016 -- this is four years ago -- an

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estimated 20.4 percent of U.S. adults, 50 million people had chronic pain; and 8 percent of U.S. adults, that's 19.6 million people, had high impact chronic pain. Those are the definitions that we just looked at from that table, right?

A We did.

Q. And CDC is not the only government agency that has been addressing the prevalence of chronic pain and the impact of chronic pain on Americans; are they?

A The only federal agency, is that what you're asking?

Q. Correct.

A I'm sure that others -- there are other discussions of chronic pain.

Q. Are you familiar with an interagency task force report on pain management best practices that was released just last year?

A I think I've seen it, yes. So 2019; is that right?

Q. That's correct.

A Yes.

Q. And that was a report put together by multiple federal government agencies; wasn't it?

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A You'd have to refresh my memory, but I think that's fair.

Q. All right. We can take a look at it, because they actually put a number on the economic impact of the CDC, the CDC figures.

First of all, Doctor, this is the cover of the report. I assume you're probably familiar with it.

A I'm sure I've seen it.

Q. Now, if we go to page 11, we will see the task force citing the CDC figures and observing that the cost of pain --

A I'm having a little trouble. I'm going to try to -- I think you kindly sent me -- may I just pull up my -- you sent me some tabs.

Can I open it, because I'm having a little trouble reading?

Q. Yeah. We can even make it bigger for you on the screen, if that helps. Just pull out the first paragraph there. Is that better?

A I'm sorry. I just don't want to be opening documents that you don't know that I'm opening. So if you can make it bigger or whatever.

MR. SHKOLNIK: Your Honor, can the

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witness be allowed to just pull up his copy
so he has it there so he can see something
above it and below it and not just a sliver?

THE COURT: Mr. Brody, are you okay with
that?

MR. BRODY: I'm fine with it. I just
have one question.

THE COURT: Good. Then we'll do that as
opposed to requiring counsel to get up on
redirect and reproducing the portions both
upper and lower. Good.

BY MR. BRODY:

Q. Doctor, I just have one question. And
that's just, you know, we see here reference to the
same numbers that we saw in the CDC report, right?

A Yes, I'm sure. I take your
representation.

Q. Well, we see 50 million and 19.6
million. Those are the same numbers we had just
looked at, right?

A Yes.

Q. And then the interagency task force goes
on to say that the cost of pain to our nation is
estimated at between 560 billion and 635 billion

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dollars annually, right?

A Of course.

Q. Now, Doctor, you have not attempted to quantify the extent to which the federal government's focus on the extent and impact of chronic pain in this country contributed to the way the medical profession has used opioid medications, correct? That's not something you've tried to quantify in your work in this case; is it?

A Sort of an effect on in 2019 on the epidemic? Is that what you're asking?

Q. My question, Doctor, was: You have not attempted, as part of your work in this case, to quantify the extent to which the federal government's focus on the extent and impact of chronic pain in this country contributed to the way the medical profession has used opioid medications; have you?

A So I definitely looked at those factors that led up to the 1990s, and I did not see prior to the 1990s the effect of the federal government as a factor, and I did look, but I didn't see that.

I'm happy to talk about other factors, but I didn't see anything about the federal

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government, so certainly I tried to look at the history.

Q. So if you looked at the history, Doctor, surely you're familiar with the fact that Alza, the company that did the research and development of Duragesic, did so specifically in response to the federal government's request of pharmaceutical manufacturers to develop agents to address pain. You must have come across that, right?

A Again, I'm not familiar with federal government's driving opioid use by Alza, but if you want to refresh my memory, I'm happy to have you do that.

Q. Okay. I didn't see any discussion of that in your expert report or material. Did I miss it?

A No. But I did identify the factors that I saw that contributed to the epidemic.

Q. Doctor, my question was a simple question. I didn't see any reference to that or to those documents in your expert report or the materials listed. I didn't miss them; did I?

A I'm not aware of such documents.

Q. Okay.

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A Of such documents. Sorry.

Q. Right. You did not. Let me ask you this, Doctor: Have you done any calculation, made any effort to quantify the extent to which medically unnecessary or inappropriate prescriptions of opioids sold by any of the manufacturer Defendants in this case led to -- let's start with addiction?

A A quantification, just so I can understand exactly what you're asking me, whether there's an association or a correlation between what and what?

Q. I asked whether you, Doctor, as part of your work in this case, made any effort to quantify the extent to which medically unnecessary or inappropriate prescriptions of opioids, medically unnecessary or inappropriate prescriptions of opioids sold by any of the manufacturer Defendants led to addiction?

A Beyond the scope. Clearly beyond the scope.

Q. So that's no, you have not?

THE COURT: Time out. Beyond the scope of what?

THE WITNESS: Beyond the scope of what I

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looked at and beyond my report. I have not
done that.

BY MR. BRODY:

Q. Same answer for opioid abuse?

A Just -- I want to make sure the
association of what about opioid abuse, sorry.

Q. I'll tell you what. I'm going to list
-- I have three more things I'm going to ask you
about. I'll list them all at once at the end of the
question so that it's clear.

You have not made any efforts to
quantify the extent to which medically unnecessary
or inappropriate prescriptions of opioids sold by
any of the manufacturer Defendants led to opioid
abuse, misuse or overdose in New York; have you?

A No. I've not quantified that. It's
beyond the scope of what -- of my report.

Q. Doctor, the bottom line is, I believe,
that you personally did not believe that you could
go in front of a court and say that you have a
learned methodology that is reproducible or
acceptable to determine the extent to which a
manufacturer is responsible for the opioid crisis;
do you?

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A I certainly have a learned methodology in front of this Court.

Q. Doctor, my question -- I want you to listen to my question, because I think you'll agree with it. You personally do not believe that you, David Kessler, could go in front of a court and say that you have a learned methodology that is reproducible or acceptable to determine the extent to which a particular manufacturer is responsible for the opioid crisis; do you?

A So I certainly do. If you -- you'll have to define extent. I have certainly a learned methodology to the fact that the manufacturers contributed by their promotional messages, right, to increased use, and that increased use led to increased risk of addiction.

I certainly have a learned -- I mean, a methodology for that.

Q. So you've sort of reached an end of the line basic sort of conclusion, if you will?

A I'm not sure I understand what you're saying "end of the line." It is -- every single statement that I have given and it was listed, you know, that promotion has an effect on prescription

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sales and appropriate prescription has an effect on sales, those sales have increased, make opioids available and availability affects the risk of use.

All those have strong support. There's no end of the line. At each one of those statements, there's multiple and multiple levels of evidence.

Q. Doctor, putting aside even the question of medically unnecessary or medically inappropriate prescriptions, you didn't do anything to try to measure -- let's just take Duragesic -- the rate of the abuse, misuse or diversion of Duragesic; did you?

A I, I, again, as I've said multiple times, I think as we've discussed, I have relied on the record and specifically companies' documents and surveys of the use.

Q. Doctor, you did a nearly identical report and employed an identical so-called methodology when you offered opinions in the MDL; didn't you?

A There are certainly areas that were explored that were broader in New York than for other areas, but the same essential, essential -- I

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mean, the report that I did for Judge Polster's case, that same methodology, I think, would be fair to say I used here.

Q. Doctor, and there, as here, in forming your opinions in the case, you did not do any specific analysis of the question of what the rates of abuse, misuse or diversion of Duragesic are, whether for medically unnecessary prescriptions or any prescriptions at all, correct?

A I, I didn't do anything outside of the record, no.

Q. And so the answer is no, you did not do any specific analysis of that question, correct?

A Well, again, analysis -- you're saying analysis. I mean, all, all the studies and data that I looked at were either company or other data. I could not generate my own data.

Q. Right. You did nothing to measure the rate of abuse, misuse or diversion of Duragesic; did you?

A Outside of the record?

Q. You didn't do any specific analysis of that question; did you, Doctor?

MR. SHKOLNIK: Your Honor, objection.

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THE COURT: Time out. Objection.

MR. SHKOLNIK: The objection is this
exact same question --

THE COURT: Asked and answered, right?

MR. SHKOLNIK: -- was asked and answered
Friday and today.

THE COURT: I got it. Sustained.

Move on.

BY MR. BRODY:

Q. Doctor, let me ask it this way: It's a
slightly different question, your Honor, and I
apologize. I think that we may be getting tripped
up, Dr. Kessler, on one term.

So I'm going to ask it differently, and
I thought I had asked it differently.

THE COURT: Go ahead.

BY MR. BRODY:

Q. You did nothing to measure, measure the
rate of abuse, misuse or diversion of Duragesic; did
you?

MR. SHKOLNIK: Objection.

Asked and answered.

THE COURT: Why is it different?

Mr. Brody, why is it different?

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MR. BRODY: It's different --

THE COURT: Hang on. Doctor, can you handle the question?

THE WITNESS: Can I handle it, your Honor? Is that what you said? Yeah, I can handle it.

THE COURT: Answer the question. Then we'll move on. Go ahead.

A No, I did not do anything outside of the record.

MR. BRODY: Can we, Ms. Radford, pull up the MDL deposition, page 572, lines 10 through 15.

BY MR. BRODY:

Q. Doctor, you were asked, in forming your opinions in this case, what, if anything, did you do to measure the rate of abuse, misuse or diversion of Duragesic, and you answered: I did not do any specific analysis on that question.

That was your testimony, correct?

A That was exactly my testimony. Again, I assume there's nothing after that, but that would be correct.

MR. BRODY: So, Ms. Radford, can we

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bring up our demonstrative again, please.

I believe we've covered all these questions, so we'll pull the last line up there, and we can cross that one out as well.

Now, your Honor, I believe that we have a copy of the final version of the demonstrative for the Court as well as for the Plaintiffs' counsel.

We ask that that be marked for identification purposes, and I also, I believe I referred to three different documents today, the task force report from 1979, we'd ask that that be marked as Defense Hearing Exhibit 1.

That the MMWR report from CDC be marked as Defense Hearing Exhibit 2, and that the 2019 pain task force report be marked as Defense Hearing Exhibit 3.

THE COURT: Did you assign a number to the Plaintiffs?

THE COURT OFFICER: No.

THE COURT: One at a time. What?

THE COURT OFFICER: It should be A.

THE COURT: No, no, not the exhibit, the

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sheet. Thank you.

We gave the Plaintiffs numbers?

THE COURT OFFICER: Yes.

THE COURT: How about from 1, 2 and 3 to B, C and D. We're already assigning exhibit identification tags as numbers to the Plaintiff. Customarily we do that here. So you can have the alphabet.

MR. BRODY: Great. Thank you, your Honor. However they're marked is fine. I just want to be sure that they're marked for the record and that the demonstrative exhibit is marked for the record as well.

MR. SHKOLNIK: Your Honor, if I could just ask a quick question because I'm now confused.

The pain management best practices report was -- what did Mr. Brody mark it as, because I'm going to reference these things.

THE COURT: Mr. Brody, can you answer that?

MR. BRODY: So the pain management was a 2019 report, and I believe your Honor indicated that would be D.

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THE COURT: Right.

MR. SHKOLNIK: D, okay. And the Carter administration report from 1979 was which?

MR. BRODY: I believe that is B.

MR. SHKOLNIK: B, thank you.

MR. BRODY: And I believe then our demonstrative is Defense Hearing Exhibit A.

MR. SHKOLNIK: Thank you very much.

THE COURT: So noted.

MR. BRODY: Thank you, Dr. Kessler.

THE WITNESS: Thank you, Mr. Brody.

MR. BRODY: And, your Honor, I have one last request, that there be a time limit on redirect.

THE COURT: I enjoy when I hear time limits because the nature, the extent and its efficiency of evidence is not necessarily connected to a time; meaning, if Mr. Shkolnik takes 25 minutes, so be it, but right now I won't assign a time limit, but if my impression is that it's becoming -- it's outside the scope of the cross-examination and -- or it's new matter, I'll end the examination.

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MR. BRODY: Thank you, your Honor.

THE COURT: Also, just a heads-up, if I sustain objections three times for asked and answered, generally I consider the examination complete.

Mr. Shkolnik, redirect.

MR. SHKOLNIK: I plan on being quick, your Honor.

THE COURT: Okay. Mr. Brody, I think he answered your question. He's going to be quick.

MR. BRODY: Thank you, your Honor.

THE COURT: We'll soon find out what that means.

MR. SHKOLNIK: Thank you, your Honor.

REDIRECT EXAMINATION

BY MR. SHKOLNIK:

Q. Dr. Kessler, good morning. And I'll be true to my word, and I will be quick. I'm just going to just quickly --

A Mr. Shkolnik, I can't -- not that it's relevant necessarily, but I can't see you. You're not in the frame. You're not even partially -- that's just me in my window. I apologize.

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Now I can see you partially, about a quarter of your face.

Q. How is that, better?

A I don't see you, but I hear you well and I'm happy to proceed.

Q. Okay. Thank you. Is there any way for this camera to be showing --

A It's just my window maybe perhaps.

THE COURT: As you move to your left, you're in full view.

MR. SHKOLNIK: There I am. Thank you.

Got it. I looked better the other way...

BY MR. SHKOLNIK:

Q. Dr. Kessler, I just want to go back to a couple of the documents that counsel asked you about, and I'm going to start with the Exhibit B, which was the report generated from the President Carter commission.

And you started to answer some questions to counsel about what was the goal of that study or that commission.

THE COURT: It looks like another app is using the camera. I'm reading what's showing up on the screen.

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BY MR. SHKOLNIK:

Q. Dr. Kessler, I'm taking a page that you were not shown from the report, and I would just like you to take a quick look at it, if you would, and I highlighted them.

A Counselor, I apologize. It may be my age or my eyesight, but there is just no way I can see that page.

Q. Okay. I'm going to read it to you to make it a lot easier, Doctor.

A Thank you kindly.

Q. There is something at the beginning of the document. It says "The foreword" and it says the Interagency Committee on New Therapies for Pain and Discomfort composed of federal commissions and scientists was created in late 1977 to assess the status of research on intractable pain and human care of dying patients and to develop recommendations in these two areas.

Is that your recollection of what the commission was focused on back in that 1979 report?

A Yes. It was on terminal cancer, terminal patients.

Q. And I want to go on and read: A primary

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objective of the committee is to promote research on the mechanism and appropriate treatment of severe pain and discomfort -- I'm quoting -- experienced by terminally ill patients, closed quotations.

Is that your recollection, sir, as to what --

A Yes --

Q. -- this panel was focusing on?

A Yes. That would be fair. It was the use of specifically of heroin, marijuana in that terminal cancer patient.

Q. I'm just going to go on in that same vein. It goes down and says: In general, the committee was formed in response to express interest of the White House -- that's the Carter administration -- and Peter Bourne, then director of Office of Drug Abuse policy, in the problems of pain and other discomforts of the dying and in fostering research on possible pain relieving characteristics of abused substances not approved for treatment in the United States.

Was that your recollection of what they were studying at that time?

A That was what they were studying, yes.

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Q. And, in fact, that panel was looking at whether or not you should be allowed to prescribe heroin to those people who were terminally ill and dying; fair statement?

A Fair statement.

Q. Does this have anything whatsoever to do with the methodology you utilized in this case and the causes of the opioid epidemic as they exist in New York, as they exist in the United States?

A I don't think so. I mean, only to the extent that it reinforces my point that prior to the 1990s, certainly strong -- the strongest opioids here, heroin, was being thought about for cancer pain, in this case terminal cancer pain.

So it reinforces what my report and what I've testified to and what no one was talking about using strong opioids for chronic back pain, or osteoarthritis, or outside of the very severe pain such as terminal illness.

Q. Thank you. Now I'm going to show you another document that counsel asked you a couple questions about. He just showed you one sentence or two sentences or a paragraph. And that is Exhibit D.

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And I'm going to put up the executive summary from the pain management best practices report from 2019. I know you're probably not going to be able to see this one either. I'm having a hard time here.

I highlighted a sentence in it, Doctor, and it says: At the same time our nation is facing an opioid crisis. That over the past two decades has resulted in an unprecedented wave of overdose deaths associated with prescription opioids, heroin, and synthetic opioids.

I just read that from the document counsel questioned you about that was issued in 2019.

Doctor, is that part of the report consistent with your methodology and your opinions in this case?

A Sure.

Q. Could you -- when the report says that we were facing an opioid crisis that over the past two decades has resulted in an unprecedented wave of overdose deaths associated with prescription drugs, is that consistent with your opinions, your methodology and the work you have done over the last

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35 years in the field of prescription medications?

A Sure.

Q. Would I be correct in stating, Dr. Kessler, that the reports from 2019 regarding best practices and how to use prescription opioids has come about because of the unprecedented two decades of deaths associated with prescription opioids?

A It certainly was -- it got people's focus, correct.

Q. And that is consistent with the methodology that you employed in this case, correct, sir?

A Yes, sir.

Q. By the way, over the years, have you been consulted with -- by other commissioners at FDA in terms of your expertise and your knowledge of the regulatory practices to assist them in carrying out their charge and their duties as FDA commissioners?

THE COURT: Just yes or no, Doctor.

Just yes or no.

A Yes.

THE COURT: Next question.

BY MR. SHKOLNIK:

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Q. You were asked a lot of questions,
quote, did you quantify, dot, dot, dot.

When you were giving answers in response
to those did you quantify questions, you repeatedly
said no, other than relying on the record.

Could you tell the Court and jury how
that comes into play.

THE COURT: There's no jury here.

MR. SHKOLNIK: Oh. Sorry. I miss
them...

BY MR. SHKOLNIK:

Q. Could you tell the Court how, how you
came about utilizing the, quote, record in terms of
this issue of quantify in response to the prior
questions?

A Sure. I'd be happy to explain that.
Should I go ahead?

Q. Yes, please.

A I mean, so if you, you know, you just
look at, for example, Mr. Brody's demonstrative, I
don't have it in front of me, but if you just take
the first one, for example, I think it was speak to
doctors. All right.

I didn't speak to doctors. I didn't

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quantify what doctors said or ask doctors why they wrote prescriptions. I didn't do that personally. But if you look at my report and you look at certain paragraphs of my report, the companies, the Defendants did that, but they did it in a systematic way.

Relying on appropriate kind of statistical methodology, they spoke to doctors, they asked doctors why they wrote prescriptions, and to the extent that it was relevant, I cited those surveys in my report in certain paragraphs, and there's a number of them.

So I didn't go beyond the record to quantitate. The quantification and the evidence is cited in the report, but the companies did that. They spoke to doctors. They asked doctors why they wrote prescriptions.

They knew, for example, message recall, the effects of their sales force, et cetera. So they surveyed doctors. I would not go out. I did not go out and quantitate separately from their own studies.

Q. Now, Doctor, I put up on the screen Mr. Brody's methodology, I'll refer to it, his

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methodology or list of things he wanted you to do.

Is that the type of things that you would do as an expert in the field of having come from FDA in terms of reaching your opinions in a case like this?

A No. If I were at the FDA or as an expert, you know, you go look -- I mean, I won't go out independently and speak to doctors or ask them why they wrote. I didn't do that when we were taking enforcement actions.

I mean, I would look at the actions of the companies and what they did, and I certainly would look at any documents that were relevant about surveys that they did, for example, their message recall, but I wouldn't go out on a sort of ad hoc basis independently to do that. That's not the way we did things.

Q. When you say "we," we as in the methodology employed at FDA over the years that you were there and since, correct?

A Yeah. I apologize. Again, the footnote, I don't represent the FDA.

Q. I understand.

A But if you go look at any DDEMAC letter

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or any enforcement letter, they are looking at the information that they received -- the companies, they wouldn't go out independently and speak to doctors or ask doctors why they wrote prescriptions.

That was not part of the methodology that was used for enforcement when I was at the agency.

Q. I'm going to just show you a demonstrative we made over the weekend, and I think we've updated it since. Can you see this, Dr. Kessler? Is it coming through?

A Correct.

Q. Okay. I have on the left side in this demonstrative Mr. Brody's methodology that he was kind enough to lay out for us over the last day where he has the red writing and the Xs.

I'm going to correct my demonstrative, and I'm going to write down Kessler methodology on the right side. Dr. Kessler methodology.

Just so it's clear, in terms of your methodology, as well as the methodology you employed having been with FDA and your experience over the years, would it be custom and practice under methodology to speak to the doctors?

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A No. Let me understand. This is to determine whether -- just so we're clear -- about whether behavior was violative, whether prescription -- whether promotion was improper, correct?

Q. Yes, Doctor. Yes, Dr. Kessler. Consistent with what Mr. Brody was suggesting in his methodology. Would you do that?

A I understand. I just want to reclarify. With regard to whether promotional activity were violative, no, FDA would not speak to doctors.

Q. I'm going to ask you the same question that he asks as his second methodology, Mr. Brody's Number 2. Ask doctors why they wrote prescriptions. Would that be the appropriate methodology employed if that was suggested?

A No. That would not be, but if there were, as there is, for example, recall, message recall studies that the company would undertake as I did hear, I think those studies that the company undertook would be relevant. And I've looked at those, but I wouldn't go out independently and ask doctors why they wrote prescriptions.

Q. And is that because you wouldn't do that if you had been doing this at the time you were with

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FDA?

A Correct.

Q. Let me ask you about the next methodology he's suggesting. Identify medically unnecessary prescriptions. Would that be something that you, as an FDA commissioner, expert, would employ in the manner in which Mr. Brody suggested you should be doing it?

A No, I would not. It would be irrelevant, I mean, at that specific level, at the individual patient level.

Q. Let me ask you the next level of evidence or research that Mr. Brody was suggesting in his methodology. Read patients' medical records. In the context that Mr. Brody asked you yesterday, would it be appropriate methodology to do that, sir?

A Never. I mean, to determine whether a promotional activity was violative, you would never. I mean, I can't see how you would do that.

Q. Let me ask you another question from Mr. Brody's methodology. Review patients' medical history is the way he suggested he wanted you to do that in order to reach opinions as to whether or not his client and the rest of these manufacturers of

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opioids improperly promoted and marketed
prescription opioids.

Would it be appropriate to be looking at
the patients' individual medical histories here in
Nassau and Suffolk County?

A No, absolutely not.

Q. Why don't you tell us why that would be
an improper methodology?

A Well, the basic methodology in
determining whether a behavior of a company is
violative or deviated would be to look at the
evidence in the label, the evidence in the new drug
application, the evidence in the medical literature
to see whether the activities of the company are
supported.

I'm not even sure how you would get the
-- where the patient's medical history is relevant
to determining whether there was a deviation. I
just don't -- I can't compute that. It would just
be outside, completely outside of any standard
practice.

THE COURT: Doctor, the issue of
relevance goes to your methodology, correct?
When you say it's not relevant, you're

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talking about your methodology, the
methodology employed by yourself, correct?

If I'm not correct, you'll tell me.

THE WITNESS: Yes, your Honor. I think
that's fair, but can I just add, that
methodology is also grounded in what I was
trained and how I did it. I mean, how we did
it at FDA.

So I mean -- so it's really -- I just
want to make sure that it's not just my
methodology, you know, that I just pulled
out. I'm trying to bring to the Court, you
know, what, how, you know, the generally
accepted approach that I, as commissioner, I
mean at FDA, would apply.

THE COURT: So you're telling the Court
the methodology that you employed was derived
from similar methodology at the FDA?

THE WITNESS: Yes, I think that's fair,
your Honor, yes.

THE COURT: Yes is fine.

Go ahead. Next question.

BY MR. SHKOLNIK:

Q. And that methodology would be the

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consensus followed under FDA regulatory schemes,
correct, sir?

A Yes, sir.

Q. And that was deemed to be reliable
methodology; was it not?

A It's certainly what our nation has used
for the last 50 years in that framework. Yes, I
think it's accepted.

Q. I'm going to just go through the rest of
this fairly quickly so we don't belabor the
point, but Mr. Brody's analysis and methodology is
suggesting you should be doing a prescription claims
analysis.

I'm not quite sure what he meant by
prescription claims analysis, but what you
understood it to mean, would that have been
appropriate under the generally accepted consensus
methodology of the FDA?

A No. I understand what he means, but
it's not something that FDA would do.

Q. Let's talk about his suggestion that you
-- Mr. Brody's methodology review aggregated claims
data. I assume that means like insurance company
claims data.

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Would that be something that would be deemed generally accepted, consensus, reliable based upon FDA methodology?

A It would not.

Q. Why not?

A Because it's not the way -- I mean, it's not relevant either to my or to FDA's methodology or approach to these questions.

Q. Mr. Brody suggested that you should be looking at the review of individual patient outcomes. You should be coming down here to Nassau and Suffolk County and track down individual patient outcomes as part of a generally accepted consensus, reliable methodology employed by the FDA. Is he right or is he wrong, sir?

A It's not the way -- it's just not the way it was done at FDA, nor would it be part of my methodology.

Q. And he then suggested that maybe you could have looked at an aggregation, an aggregation of patient outcomes of the people who have died and become addicted here in Nassau and Suffolk County in order for you to properly reach your opinions.

Would that be deemed a generally

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accepted, consensus, reliable approach?

A No. Completely beyond any methodology that the FDA would use.

Q. How about, you know, going out and picking up the phone and surveying all the doctors in Nassau and Suffolk County, would that be something that you would have had to do under FDA methodology to be deemed generally accepted, consensus, reliable? Would you have had to have done that?

A No. One would not do it that way. Again, as I said, I mean, if there were surveys that were done that were in the possession of the companies, those could be relevant, but not to pick up the phone and call individual doctors.

Q. He also suggested that you should do -- this is now conduct a quantitative analysis of New York prescribing. I didn't quite understand what that meant by Mr. Brody's methodology, but is that something that should appropriately be done in accordance with FDA methodology to be deemed generally accepted, consensus or reliable?

A It would not be.

Q. Why not?

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A Because, again, it doesn't go to the question of deviations or violative behavior.

Q. Today he added two more, two more items to his methodology: Analyze impact of pill mill illicit drugs or diversion. And I think you said you didn't do that in the way in which he phrased it.

Would it have been in accordance with generally accepted practice, FDA practices, the consensus in FDA practices or the reliability of FDA practices and methodology to do as he suggested on his examination this morning?

A No, it would not be.

Q. Why not, sir?

A Because, again, that impact of pill mills doesn't relate to whether there was a deviation or whether it was violative behavior.

Q. And, lastly, he wanted you to, once again, quantify rates of abuse, misuse or diversion. Would that have been -- when I say "he," Mr. Brody's methodology, would that have been in accordance with FDA methodology that was to be employed in your analysis in this case in order to be generally accepted, a consensus or reliable? Would that have

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been an appropriate methodology to do?

A No.

Q. Why not?

A Because, again, it doesn't go to the central question of whether there were deviations in promotional activity.

MR. SHKOLNIK: Your Honor, I have no further questions. Thank you so much.

THE COURT: Okay. I recall the Court's order indicates every witness will be subject to direct examination, cross-examination and redirect. So the witness is excused. Thank you.

MR. BRODY: Thank you, Doctor.

THE COURT: Hold on. Mr. Brody, do you have something to say?

MR. BRODY: I was just thanking Dr. Kessler for his time, and thank your Honor as well.

THE COURT: Thank you, Doctor.

THE WITNESS: Thank you, your Honor. And, again, I want to just thank the Court for allowing me to testify remotely in the pandemic. Thank you very much.

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THE COURT: No need to, but you're welcome.

THE WITNESS: Thank you, your Honor.

THE COURT: Okay. I believe Mr. Rafalski is next, correct?

MR. SHKOLNIK: Yes, your Honor.

THE COURT: We'll take ten minutes to set it up.

MR. SHKOLNIK: Thank you.

THE COURT: And I'll be back. Thank you.

(WHEREUPON, a short recess was taken.)

THE CLERK: Come to order. Part 48 is now in session.

THE COURT: By the way, I got a message during the recess that all these mics are live. So certain banter might be being picked up, so don't banter.

THE CLERK: Counsel, your appearance for the record, please.

MR. SCHMIDT: This is Paul Schmidt for McKesson.

THE COURT: Ms. Conroy?

MS. CONROY: Good morning. And I hope

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2 Honor. That was the monitor in the room I'm
3 in. Sorry. It's been corrected, your Honor.

4 THE COURT: Mr. Rafalski.

5 THE WITNESS: Yes, sir.

6 THE COURT: Good morning.

7 THE WITNESS: Good morning.

8 THE COURT: I give all witnesses three
9 pointers. It's just good common sense. Of
10 course you're going to be asked a lot of
11 questions today. The first pointer is listen
12 carefully to the question that's put to you,
13 and as best you can, limit your answer to the
14 information sought by the question.

15 Example, if I was in the witness chair
16 and a lawyer was to ask me on which street do
17 I live, I would simply offer the name of the
18 street. I wouldn't volunteer the town, the
19 state, or the ZIP code because the
20 information sought is simply the identity of
21 the street.

22 Number 2, although it's not impolite in
23 life to commence an answer before a question
24 is complete, because we save time that way,
25 especially when we know exactly where the

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question is going, of course you understand in court we require a complete record. So even though you may be certain where a question is going, wait for the question to be complete before you commence your answer, okay?

THE WITNESS: Yes, sir, your Honor.

THE COURT: Number 3, when you hear the word "objection," just stop until I give you direction, understood?

THE WITNESS: Understand, your Honor.

THE COURT: Thank you very much.

Ms. Conroy, you may proceed.

MS. CONROY: Thank you, your Honor.

DIRECT EXAMINATION

BY MS. CONROY:

Q. Mr. Rafalski, where are you today?

A I'm in Detroit, Michigan, downtown Detroit, Michigan, and I'd like to take the opportunity to thank your Honor and the Court for allowing me to do this remotely.

THE COURT: No need, but you're welcome.

THE WITNESS: Well, the two-week quarantine, I greatly appreciate it.

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THE COURT: You're very welcome, sir.

BY MS. CONROY:

Q. Mr. Rafalski, we're going to get into your background in more detail, but I want to ask you a couple of preliminary questions.

What is your profession?

A Currently I'm retired. Previous to that I was a diversion investigator with the Drug Enforcement Administration. Currently I'm retained as an expert witness by the Plaintiffs in this case. I guess that would be one of my employments.

Q. Okay. And what expertise do you bring to this case?

A The same expertise I used with DEA as a diversion investigator performing complex administrative investigations. There were more duties within my employment than that, but that was the one that I brought to -- brings me here today.

MS. CONROY: Thank you. And let me show what we have as Slide Number 2, which was your assignment in this case. Can we bring that slide up.

MR. SCHMIDT: And, Counsel, is there a way to send these slides around if you're

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going to be using them?

MS. CONROY: I believe they have been sent, but if you want to wait a second, but my understanding is they have been sent.

MR. SCHMIDT: I'll try to confirm that. I don't mean to hold you up.

THE COURT: You'll let me know if you have it.

BY MS. CONROY:

Q. Mr. Rafalski, do you see the assignment on the slide? Can you see that?

A Yes, ma'am, I can.

Q. And would you read it, please.

A Confirm that each Defendant maintained adequate control against diversion and identified blocked and reported suspicious orders.

Q. And did you do that assignment?

A Yes. That was my assignment upon being hired.

Q. Okay. And did you do that for Defendant Allergan?

A Yes, ma'am.

Q. Defendant Teva?

A Yes, ma'am.

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Q. Defendant Johnson & Johnson, Janssen?

A Yes, ma'am.

Q. Endo Pharmaceuticals, did you do it for that Defendant?

A Yes, ma'am.

Q. Did you do it for AmerisourceBergen?

A Yes, ma'am.

Q. And did you do it for Defendant McKesson?

A Yes, ma'am.

Q. Did you do it for Defendant Cardinal Health?

A Yes, ma'am.

Q. Did you do it for Defendant Walgreens?

A Yes, ma'am.

Q. And did you do it for Defendant CVS?

A Yes, ma'am.

Q. And to complete that assignment, can you tell me briefly just in categories what you did.

A Well, essentially -- not essentially. I employed the same methodology or the same investigative techniques that I utilized when I was with the DEA. It was pretty much the standard type of investigation or the way that a standard

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investigation would be completed on these type of complex administrative matters.

I first would request lots of documents. First I'd like the transaction data for the time period that I was going to analyze. I was likely to require -- I'm sorry -- to request the suspicious order policies, the standard operating procedures, any of the procedures that had to do with the maintenance of effective controls that would be due diligence type of investigations, outside communications, emails, internal documents.

And upon gaining all of those documents, I would analyze them.

Q. Thank you. And when you did that, were you using the exact same approach or methodology that you employed when you were a diversion investigator for the DEA?

A Yes, it would be the same.

Q. At DEA you would look at standard operating procedures?

A Yes, ma'am.

Q. At DEA, you would pull records randomly from sample customers?

A Yes, ma'am. Typically we would call

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those customer files.

Q. Okay. You would check to see what was reported to DEA and what was not?

A Yes, ma'am.

Q. You, while at the DEA, would ask for documents like due diligence files and transactional data?

A Yes, ma'am.

Q. And you would use the services of expert data analysts to assist in evaluating that transactional data?

A Yes, ma'am.

Q. Okay. Would you agree that there was nothing novel or unusual about that process?

A No, I would not. That's not novel. It would be a typical DEA investigation.

Q. In your experience was that methodology reliable?

A Yes, ma'am.

Q. Was it generally accepted at DEA?

A Yes, ma'am.

Q. You're being paid for your time, correct?

A Yes, I am.

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Q. And are your opinions that you have reached in this case based on a reasonable degree of professional certainty?

A Yes, ma'am.

Q. Now, mindful of the Court's comments on Friday and this morning, I would like to separate -- what we're going to talk about is two separate sections before lunch, hopefully before lunch, maybe we will go a little bit longer.

First I want to go through your qualifications as an expert witness who will be asked to offer opinions about the Defendants we listed earlier.

And second, we want to explore in more depth the methodology that you used to arrive at your opinions.

Does that sound okay?

A Yup. It sounds fine, ma'am.

Q. Now, you were first hired in this case in 2017, correct?

A Yes, ma'am.

Q. And would it be fair to say by this case, it would be the opioid litigation generally? Nationwide there were cases that were being filed in

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many jurisdictions by counties and cities against the manufacturers, the distributors and the chain pharmacies, correct?

A That's correct.

Q. And you filed a report early on in the case in the Ohio Federal Court litigation, correct?

A Yes. Typically that's called CT1, Cuyahoga and Summit Counties, Ohio.

Q. And that was last winter you filed that report, correct?

A Yes, ma'am.

Q. 2019?

A Yes, ma'am.

Q. And then about a year later or close to 11 months later, you filed a report here in the New York action in December of 2019, correct?

A Yes, ma'am.

Q. And I think you've just recently filed yet another report, and maybe others, but just last week one in West Virginia; is that correct?

A Yes, sir. Specifically the -- or yes, ma'am. Specifically the City of Huntington in Cabell County.

A Thank you.

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Q. So let's get to who you are, okay?

So if we can take a look at Slide 3, I'm going to go down memory lane here. We'll see if anybody can figure out which face you are, but in 1976 you graduated from the Wayne County Sheriff's Police Training Academy; do you remember that, Mr. Rafalski?

A I do.

Q. You know you still look --

THE COURT: Apparently mustaches were in.

BY MS. CONROY:

Q. 1976.

A That was all that was allowed, your Honor, so that was rebellion to grow a mustache.

Q. Did you always want to be a police officer, Mr. Rafalski?

A No, actually, I did not. I graduated from high school with a goal that I wanted to be a product design engineer, and the economy and other factors interrupted, you know, that goal, and I met some friends who had siblings who were police officers and became interested in the profession, and I ended up as a police officer.

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Ironically, with the sheriffs type, I went with a friend who didn't know how to come down to Detroit, navigate to take the test, and I took it with him because I was down here and I --

(Technical Skype video/audio interruption.)

MS. CONROY: Are you okay? Can you hear us, Mr. Rafalski?

THE WITNESS: I can hear you.

BY MS. CONROY:

Q. Okay. Good. Now, in 1981 you joined the Romulus Michigan Police Department, correct?

A Yes, ma'am.

Q. Okay. And you were on the force for 27 years; is that right? You're doing the math?

A Yeah. I think '81 to 2002. So I think 21 years.

Q. Okay. And Romulus is where the Detroit International Airport is located to sort of orient everyone, correct?

A Yes. Uniquely it's -- the airport is an island in the center of the city. The city is 36 square miles. Right in the middle is the airport, Detroit Metro.

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Q. And if we can take a look at Slide Number 4. Mr. Rafalski, you were one of the police officers assigned to the scene of this tragic air crash; do you recall that?

A I do. Actually, yesterday was the anniversary, and I was one of two people from the department that gathered evidence and first body recovery and then evidence at the crash site.

Q. We don't need to dwell on that tragedy, but that was one of the ways that you honed your skills in amassing large amounts of evidence in an investigation, correct?

A I think that would have probably been one of the largest incidents in trying to mark evidence and bodies and body parts to help assess the crash and recover people to their loved ones, yes, ma'am.

Q. But actually much of the time that you spent on the Romulus police force was dedicated to narcotics investigation, correct?

A Yes, ma'am.

Q. Okay. And can you describe for me while you were a police officer in Romulus, what that meant, what it meant to dedicate yourself to

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narcotic arrests and prosecutions.

A It's a unique skill that's a little above a police officer. I was tasked to run a special investigation unit, to form and run a special investigation unit in Romulus, and it coincided with the emergence of the crack cocaine epidemic.

So it was some very trying times. It essentially teaches you skills, more in depth interview skills, managing of people and interviewing of people, and learning how to navigate investigations to work up through the sources of narcotics starting at the street level and up to a higher supplier level.

Q. Now, in 1991 you were recruited to the Group 3 of the Drug Enforcement Agency field office in Detroit; do you recall that?

A Yes, ma'am.

Q. And what does that mean being recruited to Group 3 of the Drug Enforcement Agency field office?

A So during the time that I was the supervisor of the special investigations unit, we did several high level cases. And then during doing

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those cases, we sometimes requested assistance from the DEA. So I developed a relationship with some of the agents there.

And I had some cases, some ongoing cases that they wanted to invite me to become a task force officer. There's different types of task force. Mine was a little unique because I was case specific.

So when I went there I took cases and they were my cases that I worked utilizing being sworn in as a federal task force officer.

Q. Okay. And I know you told me about one very unique case that sort of attracted the attention of DEA and it involved a dumpster. Could you tell us about that investigation.

A Yes. In the course of investigating a cocaine distribution cell, a number of people that were engaged in cocaine distribution, during the investigation I identified a business in Romulus, a gentleman's club in downtown Romulus that was about three blocks from the police department as being involved in the distribution and also potentially money laundering.

So one of the tactics I used, the

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investigative techniques I used for about a seven-month, seven- to eight-month period, one day a week I would go in the middle of the night with an agent and he would drop me off and I would jump inside of the dumpster, and I would go through all of the documents inside of the dumpster in hopes of finding something useful in the investigation.

It took about eight months until I found the big moment, the second set of books and records. They were keeping two sets of books and records, and somebody had thrown them into the trash. And that started the basis for the proofs on the money laundering involving the narcotic investigation.

Q. Thank you. Now, you started at DEA and you started with some of the more -- started with criminal cases, is that correct, before you moved to administrative cases with DEA?

A Yes. But -- so my time as a task force officer was ended in 1996, and I returned back to my police department. And then, if I understand your question, now we're going to shift to when I became hired as a diversion investigator?

Q. Yes. And what year was that?

A 2004.

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Q. Okay. And when you were hired as a diversion investigator, that is when you began as a diversion investigator investigating criminal matters, correct?

A Yes. Diversion matters, but this was in the area of Detroit and the area that was jurisdiction of Detroit, the OxyContin 80 was being prescribed and abused, diverted from high level.

So when I graduated from the academy in 2004, I was immediately placed in assisting another investigator with a diversion, a doctor investigation, I think, primarily because of my law enforcement skills.

Q. And at some point did you move from criminal investigations as a diversion investigator to larger, more complex administrative investigations?

A Yes, ma'am. After about six years, the DEA did kind of a reshuffling, a reorganizing, and they shifted diversion investigators, a small number specifically to criminal investigations. And then a larger number were shifted to just do administrative investigations.

I had done quite a few criminal

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investigations, and I was kind of excited about moving from that, doing administrative investigations, something different.

Q. And when you moved to that role of doing administrative investigations, is that when you began to appreciate and broaden your experience with respect to the flow of controlled substances from manufacturers to distributors to pharmacies? Would that be fair to say?

A Yes, ma'am.

Q. And was there -- were there one or two cases that you could describe for us that helped you in that process of broadening your experience with respect to manufacturers, distributors and chain pharmacies?

A Yes, ma'am. I think first, my first six years, there were numerous investigations where they centered around pharmacies and doctors. So it gave me a good basis at the pharmacy level to understand the recordkeeping and the distribution and the dispensing.

My first actual large administrative investigation was to Harvard Drug Group, and that was -- I'm sorry.

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Q. Nope. I didn't say anything.

So can you tell us about that Harvard Drug Group investigation?

A Yes, ma'am. I was tasked -- internally we did a little investigation to see if there were any distributors in the Detroit area of responsibility that were sending Oxycodone 30 pills down to Florida.

There was an epidemic of pain clinics down in Florida at that time. Specifically there were three counties in Florida that were just a large emerging diversion problem. And one of the distributors that was identified was Harvard Drug Group. So going in in the investigation, I already had a general idea that there was distribution of Oxycodone 30 specifically to physicians, which is a little different.

Pain clinics in Florida weren't registrants in DEA registration. So the only way they could acquire drugs was to order them through the DEA number of physicians, which was a unique situation nationally.

Once I did my background information, I entered the business, and I used the DEA to style an

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investigation that we discussed earlier. I went in and requested certain kind of records. I entered that facility under an administrative inspection warrant, which is a form of a search warrant, but it is restricted to certain duties and activities.

I mirrored their server to obtain all their internal communications and directives and emails. I asked for their transaction data. That was an interesting moment, because they were more than willing to give them to me, but they asked me where the semi trucks should go, because back then we were looking at all paper records.

So we kind of shifted and worked out a way to get it electronically and confirm the data and not get all of the forms.

I asked for their suspicious order policies. All their policies actually related to maintenance of effective controls, and I also engaged in the interviewing employees.

The company was very accommodating and let me interview any employees I wanted. They gave me full access.

Q. And when you conducted that Harvard investigation, did you employ the same methodology

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that we discussed earlier this morning?

A Yes, ma'am.

Q. And was it a reliable and generally accepted methodology?

A Yes, ma'am. I think that any DEA investigator that would be tasked with this investigation would use generally the same methodology that I used.

Q. Now, after the Harvard case, you investigated another distributor; do you recall that case?

A Yes, ma'am.

Q. And what was that?

A Masters Pharmaceutical, just outside of Cincinnati, Ohio.

Q. And what did that generally, if you could summarize what that involved.

A I was assigned that investigation by the DEA management. It was a mid-size distributor, and they were also engaged in shipping Oxycodone 30 to Florida. This time this distributor was shipping it to pharmacies, and they were shipping it in massive numbers.

Masters Pharmaceutical, I think, at

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times was at least in the top five of all distributors in the United States that were sending Oxycodone 30 products to Florida.

Q. And what time period is this generally?

A I started my investigation there in 2011.

Q. And the investigation that you conducted of Masters, did you employ the same methodology that we discussed this morning?

A The same general framework. All the investigations are a little bit different. On this one, I did not use an administrative inspection warrant. Most of the things that I obtained initially was on-site. I did some initial interviews, and I looked at some customer files on-site.

Subsequent to that, I served an administrative subpoena to gain the same kind of record I discussed in the Harvard case, customer files, internal emails, internal documents, all of the policies related to the maintenance of effective controls.

I used the on-site opportunity to look at a customer file, some specific customer files in

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the presence of some of the compliance personnel,
and some good things come out of that.

I still recall I was looking at a
customer file, and the vice president interrupted --
interjected that that was a pharmacy that
specialized in diabetic treatment or diabetic
medications.

So I was looking at the utilization
report, which is a list of all the drugs dispensed,
and Oxycodone was at the top 30 in really large
numbers and all --

(Technical Skype audio/video
interruption.)

MS. CONROY: We've lost you,
Mr. Rafalski. I don't know if you're still
talking and can hear me.

THE COURT: Any tech people around?

THE WITNESS: I've lost the feed.

THE COURT: Okay. Hang on a second.

MS. CONROY: Oh, there you are, there
you are.

BY MS. CONROY:

Q. You were just starting your conversation
about the diabetes comment made by the officer at

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Masters.

A Yes. The vice president, he was also a pharmacist, a registered pharmacist. And I spun the file around and slid it across and I said, You're a pharmacist. I'm not.

I said, Could you take a look at me and tell me which drugs are useful in treating of diabetics. And the first look on his face, I could tell what the answer was going to be. He looked at it and he said, I don't really see any on here.

I took the file back. I didn't really address it at that time, and it kind of gave me an indication of where the investigation was going to go.

Subsequent to that I served two administrative subpoenas, and I took a number of customer files. And then subsequent to gaining all the information I needed, I returned back to Detroit, and I started to analyze in the same way that I did from the investigation here in New York.

Q. Okay. And now you've described two distributor investigations.

Was there an opportunity to then look at a manufacturer who was also a distributor while you

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were a diversion investigator?

A Yes. Based on the information that I learned in conducting the Harvard case and the Masters case, specifically in the Harvard case, there was a discussion in the hallway, just a general discussion with the compliance director, and he made a mention of a thing called chargebacks.

And that that was a visibility that the manufacturer could see the distribution of their products all the way down to the pharmacy level. That was kind of what I guess you call them an aha moment.

I didn't really address it with the compliance. We talked about it in general terms. I didn't want to show my excitement, but I thought that was gonna be really useful down the line.

When I did the Masters investigation, some of the interviews were with corporate personnel, and they basically indicated that Mallinckrodt also used these chargebacks and that gave them visibility where their product was being distributed.

So when I started the Mallinckrodt case, it was with the understanding that Mallinckrodt had

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full visibility of their products being distributed to Florida, specifically the Oxycodone 30 and the Oxycodone 15 milligram products.

I did not go on-site with Mallinckrodt, but I started the investigation the same way. I did some preliminary research on the company, any previous administrative actions, a history, and then to initiate the investigation, I served an administrative subpoena, and I requested all of the same documents I discussed previously for the Harvard and Masters case, and the same type of documents I've used in my evaluation with this litigation.

Q. Thank you. And when -- you talked about at Masters going on-site. Were you on-site at a distribution center?

A Yes, ma'am.

Q. Okay. And can you tell me, have you ever been on-site for any of the Defendants' distribution centers?

A Yes, ma'am.

Q. Do you recall which ones?

A I've been on-site for AmerisourceBergen. I've been on-site with McKesson. I think that would

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be the only two.

Q. Okay. Now, Mr. Rafalski, is it fair to say that you have spent years investigating diversion prevention, controls and suspicious order monitoring systems with respect to controlled substances?

A Yes, ma'am.

Q. And what I'd like to do is quickly go over the components of those systems.

Now, you are very familiar with the Controlled Substances Act, correct?

A Yes, ma'am.

Q. Okay. Let's just start with the basics, if we can look at Slide 5. Now, the Controlled Substances Act talks about a closed system.

Can you describe what a closed system is in the context of suspicious order monitoring and drug diversion.

MR. SCHMIDT: I'm sorry to interrupt.

Your Honor, I just got a note from Mr. O'Connor, who is designated manufacturer counsel and also counsel for Mallinckrodt, that he's been unable to object to some of those questions regarding Mallinckrodt. So I

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2 think he's on the line, but on mute somehow.
3 I don't know if there's a way to unmute him.
4 I apologize.

5 THE COURT: Can he turn on his mic?

6 Just tell him to activate his mic on his
7 end and then speak up.

8 So there's an objection in connection
9 with testimony that deals with Mallinckrodt;
10 is that correct?

11 MR. SCHMIDT: I think that's generally
12 right, your Honor, but I'm not in a position
13 to articulate that for him.

14 I assume if we're not hearing him, he's
15 still having the mic problem.

16 THE COURT: That's Mr. O'Brien you said?

17 MR. SCHMIDT: O'Connor.

18 THE COURT: Mr. O'Connor, you can
19 probably hear me. There's a way for you to
20 access your mic. Now I'm probably the last
21 person in this courtroom to tell you how to
22 do that, but I suspect that there's an icon
23 somewhere on the screen with a line through
24 it, that if you depress that icon, your mic
25 will be activated. Am I right?

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TECHNICIAN: So we just checked. He isn't muted on his computer. He is not muted on his computer. So he may just need to reboot his computer and join again.

THE COURT: Mr. O'Connor, you may have to reboot your computer. So why don't you take a few minutes and do that.

MR. SCHMIDT: And, your Honor, I received a subsequent note from Mr. O'Connor saying he's having his IT people check his connectivity, but we should proceed in the interim.

Perhaps we should just note his objection later. And thank you for accommodating us, your Honor.

THE COURT: Okay. Go ahead.

BY MS. CONROY:

Q. Mr. Rafalski, if you could just describe for us what is meant by the closed system.

A Yes. The regulations were designed to -- one of the key reasons was the prevention of diversion. And the closed system in this picture is designed that there is a recordkeeping and security in place to ensure as the drugs flow through the

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1 system, typically through these registrants,
2 importers to the manufacturers to the distributors
3 and to the pharmacies, that there is recordkeeping
4 and security to keep the drugs contained within the
5 closed system so they don't leak out and be
6 diverted.
7

8 There's many more registrants in this
9 that could be in this closed system, but all of them
10 are bound by those regulations to maintain the
11 integrity of the distribution and no diversion.

12 Q. Thank you. And if we could now turn to
13 Slide 5, and here we have some of the requirements
14 and regulations associated with the Controlled
15 Substances Act and some of the implementing
16 regulations that you were familiar with as a DEA
17 diversion investigator, correct?

18 A Yes, ma'am.

19 Q. Okay. And if you just look at the first
20 bullet point where it says, Registration program for
21 manufacturers, distributors and dispensers of
22 controlled substances. What does that mean, a
23 registration program?

24 A Companies that want to attain DEA
25 registrations in these business categories have to

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1
2 apply to the DEA for a license, and there is an
3 actual set preregistration investigation that the
4 DEA would conduct to prior to issuing DEA licenses
5 to these different business types.

6 One, before even the DEA even moves
7 forward that they would require all of these
8 different business types to obtain a state license,
9 and then once that's obtained, then the DEA moves
10 forward. It's typically called a preregistration
11 investigation, and that usually or almost always
12 includes an on-site or multiple on-site visits and
13 meetings at the manufacturer and distributor level
14 where there is an evaluation of business practices
15 and security requirements to ensure that before the
16 license issues, they're in compliance with the law
17 and the federal -- the CFR, Code of Federal
18 Regulations.

19 Q. Okay. And then the second bullet point
20 is, Must maintain effective control against
21 diversion of particular controlled substances.

22 What does that mean?

23 A That's both in the law and the
24 regulations, and that's the overarching or the goal
25 of the whole security section is that all of the

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duties that are contained in the security section are all designed that the registrant must maintain effective controls against diversion of particular controlled substances and the prevention of diversion.

Q. And that applies to any registrant, correct, a manufacturer, a distributor or a pharmacy, correct?

A Broader than that. Every registrant that that applies to their handling of controlled substances.

Q. Okay. And the third bullet point requires each registrant to report suspicious orders of controlled substances. What does that mean, the reporting of a suspicious order?

A It's contained in the regulation in regards to suspicious orders. It actually requires each registrant design and operate a suspicious order system. And when discovered, that's what's called a suspicious order, then it must be reported upon discovery to the DEA.

It also gives three -- not exclusive, but three types of ways to look at orders to monitor whether or not they're suspicious, unusual size,

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unusual frequency or -- and then unusual pattern.

Q. Okay. And if we can go to the next slide, we'll look at some of these requirements in a little more depth.

So to maintain, any registrant in order to maintain effective controls, one of the first things they need to do is have a comprehensive system to evaluate new customers or a know-your-customer system.

Are you familiar with what that is from your experience at DEA?

A Yes, I am.

Q. And how would you describe it?

A That's sometimes called an onboarding. So this is when we can talk -- an example in this case is a distributor is making a determination that they want to take on a new customer, a new retail pharmacy.

So they have to conduct some evaluation to get to know that customer. They have to evaluate what their business model is, what types of drugs they want to use in what types of quantities. They have to make all of these evaluations first to believe that this customer is actually a viable

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business to handle drugs.

They also would use this evaluation to determine what types or what quantities of drugs they want, and that's typically the second bullet threshold, and they have to set those thresholds.

Now, that is a new customer that's never handled drugs before. And in this case in the United States, retail pharmacies often jump from distributor to distributor sometimes purely for price reasons or sometimes there may be other regulatory or diversion problems.

So that's a different kind of onboarding. Still it's the same. It's a know your customer, but in that case, the distributor has a little more information that they can gain and analyze because there's previous conduct before they make their determination on, one, whether they want to accept the customer, and where they expect the threshold and the types of drugs they want to sell to them.

That's just a narrow example between distributors and pharmacies. There are different examples of different customers, but I'm not going to get into all of those.

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1 Q. Okay. When you did the Masters
2 investigation, you looked at customer files,
3 correct?
4

5 A Yes, ma'am.

6 Q. And that's pretty much what you're
7 talking about here, those know-your-customer files?

8 A Yes. That would be a part of a customer
9 file. A customer file would be all of the -- I
10 would expect to see all of the due diligence and all
11 of the interaction that would be specific to the
12 maintenance of effective controls, which should be
13 contained in that customer file in paper, electronic
14 or a combination of both.

15 Q. If we look at the next bullet point, how
16 are thresholds related to effective controls?

17 A It's an important assessment for a
18 distributor when deciding to distribute drugs to a
19 customer; in this case discuss specifically a
20 pharmacy.

21 So they have to do an evaluation on how
22 much drugs they are going to sell by type, size, the
23 quantities. Typically they look at it on a monthly
24 amount, and they have to determine what the company
25 can legitimately dispense during a monthly period.

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That's done through evaluation of previous conduct or a distributor can analyze other similar size pharmacies in the same geographic area. They can use all of their data that they gained from their business activity to get a good handle on what would be a good starting threshold.

Q. Okay. Then the next one is, Next way to maintain effective controls is for a registrant to design and operate a system to track orders of unusual size, deviations from a normal pattern and an unusual frequency of orders.

I think you touched on this a couple of minutes ago, but can you explain what you're looking for when you are trying to determine whether or not there is a system that will maintain effective controls.

A This is basically called a suspicious order system, and it's whether or not the company has actually designed a way, typically electronic, but it's not required by the law to be electronic, and it's a way that a company that's going to distribute drugs can monitor the orders that they're sending to make sure that they don't break these thresholds, these levels that have been set for

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legitimate use.

Q. Okay. And then we see the next bullet point, Conduct due diligence of orders flagged as suspicious. And let's just take the first part. What does that mean?

A So when an order reaches and exceeds that threshold, there's an expectation that the company would stop shipment because that would be something outside of the usual. It would be suspicious, and they would conduct due diligence to understand why it was flagged.

Many cases it's as simple as calling the registrant and asking them if -- I think they call it a fat finger order -- if the registrant wanted one and they ordered 11 or they wanted 10 and they accidentally ordered 100.

Some of the orders are typically cleared just because they were incorrect or error orders. If that's not the case, then that's where the due diligence needs to be conducted, and they have to get an understanding of why the order exceeded what they had established as a threshold, a legitimate use.

There could be an explanation, and so

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they start an investigation. They look at previous history, and then they get an explanation on why they potentially want to increase the amount. It's not just what the registrant tells them.

If the registrant was just to say, I'm doing more business, that would not be in itself just a sufficient reason.

Another one may be a new pain clinic opened. The expectation is they would actually verify some of the things or the things that they were told by the pharmacy independently to make sure that that actually is what is occurring and that these drugs can be handled safely and not be diverted.

THE COURT: Excuse me. Is that trigger on this due diligence, does it occur on the very first order that exceeds the thresholds, or is there a pattern?

THE WITNESS: Your Honor, it would be the very first order. That would be the expectation.

THE COURT: So if one order, let's say, in March exceeds by whatever, whatever number, whatever percentage of February, the

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due diligence aspects of the steps are triggered?

THE WITNESS: I think it's a little -- not quite exactly like that, your Honor. I mean, that could be one way.

I think if they set a threshold average maybe by -- if I could give you an example. The previous 12 months order patterns and they've established an average over the last 12 months, and now you're in the 13th month and the order amount that exceeds that average, that potentially could be a trigger.

Let's just theoretically say it was 20,000 pills. So any order that exceeded that 20,000, that would stop the shipment, and that would require some kind of a due diligence investigation to understand why they're ordering a greater amount.

THE COURT: Exceed the 20,000 by how many? How much?

THE WITNESS: Your Honor, it could be one bottle of 100 pills.

THE COURT: Okay. Thank you.

THE WITNESS: You're welcome.

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BY MS. CONROY:

Q. The next bullet point is the due diligence must be robust, well documented and retained. Why is that? Why must it be well documented and retained?

A It paints a historic picture for the distributor, the person doing the evaluation. I kind of liken it to your family doctor. If you went to your family doctor and there was no records kept, every time you went, it would be a start over again of your symptoms, and there would be no history.

I think it's important that the companies are able to look back and see if they've conducted previous due diligence investigations, if there's been prior adjustments to the thresholds and what investigations were previously completed.

I would expect those to be retained and be available for review.

Q. And if we just go back to the Judge's example, would that be important, for example, if there was -- the threshold was exceeded, say, in March, would it be more, if that were to happen again, to have some sort of a record to understand why that may have happened if it were to occur

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again?

A Sure. If what you're indicating is there's a pattern of exceeding the thresholds, I think it's important to maybe take a little deeper look or a deeper dive at why they're continuing to exceed the threshold.

It could be, it could be a legitimate increase in business, and that's why the due diligence investigation is completed, but it also, there may be also some issues involved that are potentially diversion.

Q. And the last bullet point is that the suspicious orders must be reported to DEA when discovered. What does that mean, "when discovered"?

A That's in the regulation, and that's when the registrant, when that order is triggered and it's a suspicious order, that they're obligated to report it.

Now, just for clarification -- well, not clarification. So two things actually can happen, your Honor. So the suspicious order could trigger the stop, and it doesn't always require due diligence.

If the company decided that they were

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going to report the order and not ship those drugs any longer, then that would be the end of it. They wouldn't do due diligence.

But once the system stopped the order and if they determined they desired to continue to ship that product, then they would conduct their due diligence to alleviate the suspicion before they shipped it.

Q. Now, before we really wrap up and talk about an overview of your methodology, I want you to specifically address your report in this case, and let's just mark for identification your report.

Do you want one, your Honor?

THE COURT: It looks like you have a spare. I'll take it.

MS. CONROY: I'm happy not to take them back home again. We would mark this as Plaintiff's Exhibit 1 for identification.

(WHEREUPON, the report was hereby marked as Plaintiff's Exhibit 1 for identification.)

MS. CONROY: Now, if I can go to the next slide.

THE WITNESS: I hope your Honor doesn't compare how I look today to then.

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BY MS. CONROY:

Q. The slide struck me because I have fond memories of those typewriters. Phones don't look all that different, but you were drafting investigation reports and such using a typewriter like that years ago, but times have really changed. Would you agree?

A Oh, yes, they have. I would agree.

Q. And you have prepared -- I think we talked about it a little bit -- some really significant reports in your career at DEA. Masters comes to mind. That was a gigantic report, correct?

A Yes, ma'am.

Q. And in this we talked a little bit about the report that's been filed in this litigation and we can see from Exhibit 1, it's a very significant report and quite in depth, lots of documents cited, correct?

A Yes, ma'am.

Q. Do you endorse everything that is in this report, Exhibit 1, your report?

A Yes, ma'am.

Q. Now, did you receive any assistance from any lawyers in preparing this report?

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A Yes, ma'am.

Q. Could you describe for me what kind of assistance you received.

A First and foremost is the amounts of documents in the case are very huge. I had to request or to gain access to the documents I need for my methodology, I request them from the attorneys, the types of documents, and sometimes or many times I might go back and ask for additional documents related to -- to form my opinion to gain those documents. That's one of the things where I need assistance.

Q. So would it be fair to say that you have categories of documents that you request that the lawyers or the lawyers' offices help you in retrieving?

A Yes, ma'am. Actually, at the very onset there was some discussions on what documents I would need to conduct my investigation. So I think the requests early on were fashioned so that the discovery request would, would obtain those type of documents, yes, ma'am.

Q. Okay. And at any point up until today, have you ever asked any of the lawyers, or their

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staff, or the law offices for any document and were told that you couldn't receive it?

A No, ma'am.

Q. Now, I think you know from a deposition that was taken in this case that the defense lawyers have tried to assert that you cut and pasted sections from the New York Complaint into your report.

Can you explain what that's all about, what you actually did.

A Yes, ma'am. I've obviously thought about that a lot since my first deposition. It essentially, it isn't a cut and paste. I didn't take them out of the Complaint and place them into my report. Those, those passages or sections came to me from the attorney that I worked with, and I knew that they were provided to me by the New York AG's office.

I got them, and I evaluated, and I looked at them. I found them to be more of a factual representation of what was occurring in New York. I evaluated the statements. I looked at the supporting documents.

In some cases I asked for further

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verification of footnote material or to substantiate what the statements were. At some point I adopted them in my report.

I did not know that they were taken directly from the Complaint, but I knew that they were in my report, yes, ma'am.

Q. And you stand by your report, correct?

A Yes, ma'am.

Q. All right. Let's move now to Slide 8, and let's just take a look at an overview of the methodology that you employed in this case.

And as I think we've said several times this morning, would you agree that the methodology you employed in this case is the same methodology that you employed in your tenure at DEA?

A Yes, ma'am.

Q. And the first bullet point is the application of the regulatory framework set out in the Controlled Substances Act. Do you agree that that was a part of your methodology here?

A Yes, ma'am.

Q. Is there anything unusual about applying the regulatory framework of the CSA?

A There's nothing unusual about that,

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ma'am.

Q. And then the next piece of your methodology is to collect Defendants' transactional data.

Now, there's all sorts of data held by Defendants, depending on the type of investigation that you are conducting, but is that always a part of your methodology, to collect the transactional data?

A That's always at the core of the investigation, whether it's the administrative work at the DEA or whatever is conducted in the methodology for the MDL.

I mean, that is the transactional data is the sale of controlled substances, the distribution. So it's obviously at the core of my evaluation.

Q. And the next bullet point is to review Defendants' compliance program. And we're going to go through the pieces quickly of the compliance program, but just generally explain why it is that you want to know what the program looks like.

A To get an understanding on whether it meets the criteria of maintaining effective controls

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1 to prevent diversion, whether these things occurred.
2
3 And, well, on some of them, I'm looking at documents
4 and information to see if some of them occurred, and
5 I'm looking at other things listed on this list to
6 see if the company was in compliance and whether
7 they were carrying out their responsibilities.

8 Q. So let's look, first of all, at the
9 standard operating procedures. And those operating
10 procedures also include record retention policies.

11 Was that a part of your standard
12 methodology while you were at DEA to look at those
13 procedures?

14 A I'm sorry, yes, ma'am.

15 Q. And it was part of your procedure and
16 methodology here in this case, correct?

17 A Yes, ma'am.

18 Q. Now, the next one is a review of the due
19 diligence files, the suspicious order monitoring and
20 know-your-customer materials; do you see that?

21 A Yes, ma'am.

22 Q. And was there anything unusual about a
23 review of those materials?

24 A No, ma'am.

25 Q. That was part and parcel of what you did

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as a DEA investigator, and you continued that methodology through to this expert report, correct?

A Yes, ma'am.

Q. The next one is investigations, interviews and witness statements.

You didn't talk very much about that, but could you give a brief description of what that category means?

A Whether there are any previous investigations conducted by federal or state units, kind of the history or the background. Interviews, in this particular case I don't have access or I don't think I have access to go out and conduct my own interviews at these companies.

I rely on the depositions more as the interviews and also witness statements. So I guess that would be one in the same.

Q. Okay. And then also you would review internal company communications and documents; do you see that?

A Yes, ma'am.

Q. And that's something you did while at DEA, correct?

A Yes. That was a critical part of my

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administrative investigations.

Q. And was it a critical part of your methodology with respect to this expert report?

A Yes, ma'am.

Q. And the last bullet point, Prior administrative actions; what is that?

A Those particularly were with the DEA. I wanted to see if there was any, any cases that previously occurred with the DEA where there was administrative action, specifically in regards to the maintenance of effective controls, how the company responded, what the basis for the case was, and kind of just lead -- just get an understanding of the history of the company.

Q. And the final bullet point is your review of data resulting from metrics applied by data analysts. It's a little thick, but really -- well, you explain it. What does that mean?

A Both at the DEA and in investigations for the MDL and the State of New York, there might be occasion to take data and this would be transaction data, and I would ask a data analyst to do some analysis, apply a metric.

It's way outside of my skill set to do

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that. So I rely on the people that are experts,
both at the DEA and the litigation here in New York.

Q. And that would have been a part of your
methodology to ask data analysts to review so that
you could see what their results were and determine
whether or not that was an area that would impact
whether or not there were effective controls, is
that fair?

A Yes. That would be one of the primary
reasons, yes, ma'am.

Q. Was there --

MS. CONROY: Your Honor, I have about 10
or 15 more minutes. Should we just continue
on or should we break for lunch?

THE COURT: When you say you have "10 or
15 more minutes" --

MS. CONROY: Correct.

THE COURT: -- to complete what?

MS. CONROY: To complete my direct.

THE COURT: We'll complete it now.

MS. CONROY: Okay. Great. Thank you.

Q. Mr. Rafalski --

THE COURT: Let me ask him a question.
What's a metric?

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1 THE WITNESS: A metric would be, let me
2 give you an example, your Honor. A metric
3 would be to apply a suspicious order system.
4 Let's say that a company had a suspicious
5 order system where they were doing a rolling
6 average, a one-year 12-month rolling average,
7 which means they take the cumulative
8 purchases of Oxycodone every month for 12
9 months and gives an average, and their
10 suspicious order system then says that they
11 would allow a company to purchase three times
12 the amount of the average, I might take all
13 of the transactional data and see how many
14 orders would trigger that system.

15 THE COURT: So a metric is an
16 application process?

17 THE WITNESS: Yes. It would be the
18 formula to conduct the analysis on the data.

19 THE COURT: Okay. Thank you.

20 THE WITNESS: To do the average and then
21 do the three times, yes, sir, your Honor.

22 THE COURT: Got it. Thank you.

23 THE WITNESS: You're welcome.

24 BY MS. CONROY:
25

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2 Q. And, Mr. Rafalski, sometimes in this
3 litigation we call those metrics algorithms or
4 formulas that are applied to the shipment data to
5 determine whether or not a particular month or a
6 particular group of months was over or under a
7 threshold, correct?

8 A Yes. Most typically, algorithms are not
9 usually metrics, but that's just the terminology
10 they're using in the litigation here.

11 Q. Now, one thing I think we would like to
12 clear up a little bit is whether or not it's
13 possible for you conducting the methodology that you
14 did in this case, are you identifying actual, an
15 actual diverted order in, say, for example, Suffolk
16 County, New York?

17 A No, ma'am.

18 Q. And why is that?

19 A First and foremost, is when I met with
20 the attorneys and they gave me the guidelines or the
21 boundaries of what my responsibilities were and what
22 opinions I should, I should work on, it wasn't
23 looking at specific orders. It wasn't one of the
24 requirements.

25 And, essentially, I can't tell you what

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1 was actually diverted, but my opinion is more likely
2 than not that these orders were diverted.
3

4 Q. And would you, when you did, for
5 example, Masters or the Mallinckrodt investigation
6 or the Harvard Drug investigation, you were not
7 looking either at specific diverted orders, correct?

8 A In none of those cases did I ever have
9 to actually look at and find a specific order that
10 was diverted. And practically, in a practical
11 sense, it's not impossible, but only one of the few
12 scenarios where you could look at a specific order
13 and whether that specific order would be diverted
14 would be if I happened to be at the pharmacy when
15 the distributor truck came and they opened the door
16 and they handed a box of pills to somebody and they
17 put them in their trunk and drove away. I mean,
18 then I could say that particular order.

19 But to go back for diversion and look at
20 specific orders, it's, it's -- I'm not saying it's
21 impossible, but it's just, it's just not necessary
22 in looking at the overall failures by the companies.

23 Q. And when you were a diversion
24 investigator and you were doing your administrative
25 investigations, it would not have been a part of

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2 your methodology to go one by one with those
3 potentially diverted orders; it was different,
4 correct?

5 A Yes, ma'am. I never did it order by
6 order.

7 MR. SCHMIDT: Objection, your Honor.
8 Leading.

9 THE COURT: And the nature of your
10 objection, sir?

11 MR. SCHMIDT: Leading.

12 THE COURT: Oh, leading?

13 MR. SCHMIDT: We've been leading for
14 quite some time.

15 THE COURT: Everybody has been leading
16 for two days. I assure you I will give you
17 the same exact leeway that anybody else is
18 taking in terms of leading.

19 You know, a leading objection, of
20 course, is very significant when there's
21 people sitting in that box over there, the
22 jury box, the civilians.

23 I recognize they're leading questions.
24 I'll allow both sides to lead when necessary;
25 however, if it is indeed a critical aspect of

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the direct testimony, I will ask you,
Ms. Conway, not to lead.

MS. CONROY: Thank you, your Honor. I
know. I'm looking at you on the screen
instead of right at you.

BY MS. CONROY:

Q. Mr. Rafalski, have you understood all my
questions today?

A Yes, ma'am.

Q. And is there anything that you would
like to correct or change?

A No, ma'am.

Q. Was your testimony about the methodology
that you used in formulating your opinions based on
your education, training, and experience, first of
all, as a police officer and then as a diversion
investigator for DEA?

A Yes, ma'am.

Q. Was the methodology you used in
formulating your opinions in this case the same
methodology you used in your role as a diversion
investigator for DEA?

A Yes, ma'am.

Q. Are your opinions in this case based on

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a reasonable degree of professional certainty?

A Yes, ma'am.

Q. And although we didn't discuss all of the factual bases for your opinions, are the facts upon which you relied in formulating your opinions disclosed in your report, Plaintiffs' Identification Exhibit 1?

A Yes, ma'am.

MS. CONROY: Pass the witness, your Honor.

THE COURT: Okay. We'll recess.

MR. O'CONNOR: Your Honor, if I may, this is Andrew O'Connor from Mallinckrodt.

THE COURT: How are you, Mr. O'Connor? I can see you now.

MR. O'CONNOR: I just want to make sure my objections were clear for the record. I did attempt to object to the line of questioning about Mallinckrodt on the basis of that testimony is prohibited by federal law.

Mr. Rafalski received a letter from DOJ to this effect, that he was not to rely on or disclose nonpublic information during the

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2 course of his investigation.

3 (Technical Skype audio/video
4 interruption.)

5 THE COURT: Are you near an airport?
6 Maybe a landscaper with a leaf blower.

7 I understand your objection. The Court
8 will not consider that type of information.
9 As a matter of fact, I believe Judge Polster
10 made a similar ruling that -- this would be
11 his Number Docket 2494, I believe -- yeah,
12 2494. So I'll sustain your objection.

13 Let's break for lunch. Two o'clock.
14 Make it a little extra. They have to police
15 all three courtrooms, you know, the security
16 people. So around 2:10, okay? Thank you.

17 MS. CONROY: Thank you, your Honor.

18 (WHEREUPON, after a luncheon recess, the
19 following was had:)

20 THE COURT OFFICER: You can remain
21 seated.

22 THE CLERK: Part 48 is back in session.

23 THE COURT: Good afternoon, everybody.

24 THE CLERK: Good afternoon, Judge.

25 THE COURT: You can sit down.

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Mr. Rafalski, how are you?

THE WITNESS: I'm good, your Honor,
thank you.

THE COURT: Remind the witness, please.

THE CLERK: Mr. Rafalski, I'll remind
you you're still under oath.

THE WITNESS: Yes, I know that. Thank
you very much.

THE COURT: Now, I understand we have
three lawyers that have asked for the
permission to cross-examine the witness. If
not, Miss Conway has no further questions,
who's up?

MR. SCHMIDT: I think I am, your Honor.
Paul Schmidt from McKesson. I think there
might be a brief question at the very end for
one additional lawyer on the defense side,
one of the lawyers in court.

May I proceed, your Honor.

THE COURT: Yes.

MR. SCHMIDT: Thank you.

CROSS-EXAMINATION

BY MR. SCHMIDT:

Q. Mr. Rafalski, it's good to see you

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again. I'm sorry, we're seeing each other remotely, but I thank you for joining remotely, just as I thank the Court for the opportunity to be here remotely.

I'm probably just going to spend a little bit more time than Miss Conroy did going through some of your methodological points and how you got to your opinions just to put a little meat on the bones of what you talked with Miss Conroy about. In doing that, I'm going to try to be as efficient as possible, including asking a lot of yes or no questions. I'll ask you to do the same in your answers, be as efficient as possible. If you can say true, false, please do so. If you can say yes, no, please do so. Fair?

A Yes, I understand. If I can answer the questions in those manners, I will.

Q. Thank you, Mr. Rafalski.

Do you have handy your report which the Plaintiffs marked as Plaintiffs' Exhibit 1?

A Yes.

Q. I may refer to that at different times, but I want to ask you some foundational questions about the process that went into your report.

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Do you understand that it's important that your report be accurate?

THE COURT: Give me one second. Just hang on. I received a note. I don't get this. Asking counsel to speak into microphone.

THE COURT OFFICER: Everyone who is in the room, before you speak just make sure you are right in front of a microphone, because the people online are having trouble hearing your objections and what you're saying in the courtroom.

THE COURT: You said it better than I could. Thank you.

MS. CONROY: Understood.

Q. Sure. Just to re-ask the question, do you understand it's important that your report be accurate?

A Yes, sir.

Q. Do you agree that it's important that the words in your report be your own words and not the words of the lawyers?

A Yes, sir.

Q. Do you still stand behind your report

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being your words and your opinions in this lawsuit
and not the words of the lawyers?

A Yes, sir.

Q. You understand it's important that your
report be complete, correct?

A Yes, sir.

Q. And I had the chance to depose you back
in February regarding your report; do you remember
that?

A Yes, sir.

Q. You told me then that you were ready to
testify fully regarding the opinions in your report;
is that still true?

A Yes, sir, it is.

Q. You told me then that there was no
further work that you needed to do in order to be
able to testify based upon what you knew then; is
that still true?

A Yes, sir, it is.

Q. You told me you would come back to me
and let me know if you did have something new you
needed to do and you have not done that, correct?

A That is correct.

Q. You provided no supplement to your

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report, no new list of materials to review, correct?

A I only provided an errata.

Q. To the actual deposition, correct?

A Yes, sir.

Q. Okay. Guided by the Judge's July 31st order, Mr. Rafalski, what I'm going to do is really focus on your methodology, the processes you used and how it was you got from the data you were given to the opinions that you reached; does that make sense?

A Yes, sir, I understand.

Q. So to set the stage on that, before you gave a report in this New York case, you gave a report in a federal case in Ohio; is that correct?

A Yes, sir, that's correct.

Q. That Ohio report included a discussion of Ohio pharmacies, alleged suspicious orders in Ohio and conduct by manufacturers and distributors in some pharmacies in Ohio, correct?

A Yes, sir.

Q. That report did not talk about New York pharmacies, New York suspicious orders or conduct by distributors, manufacturers or pharmacy Defendants in New York, correct?

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A Not specifically in that report.

Q. And so when you took that report and adapted it for this case, you had to adapt it with New York specific facts, correct?

A That's only partly correct. Some of the information contained --

Q. Let me just ask you, did you adapt it to specifically information on New York pharmacies that did not appear there before?

MS. CONROY: Objection, your Honor.

The witness was attempting to answer the question.

THE COURT: Again?

MS. CONROY: The witness was attempting to answer the question, and he was interrupted.

MR. SCHMIDT: I don't think I interrupted. I think he paused and then I asked my question.

THE COURT: It's easy. Mr. Rafalski, did you finish your answer?

THE WITNESS: I did not, your Honor.

THE COURT: Finish your answer and then we'll move on to the next question.

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THE WITNESS: Okay, finish my response.

It wasn't a completely new report because many of the things in my Cleveland -- my Ohio report were corporate national policies, so there were portions of the report that carried over into the New York report. Just so it's clear that it wasn't a completely new report.

Q. I didn't ask you that. I just said you had to adapt it, correct?

A Um, yes. That's how I interpreted it, I'm sorry.

Q. You added new opinions, for example, regarding pharmacies in New York, correct?

A Yes, sir.

Q. You added new opinions regarding alleged suspicious orders in New York for some of the Defendants in this case, correct?

A Yes, sir.

Q. You added opinions regarding manufacturing and distribution and chain pharmacy activity in New York, correct?

A I think my opinions were consistent with the previous report.

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1 Q. Did you add new opinions regarding
2 manufacturing and distribution in chain pharmacy
3 activity in New York or do you not have such
4 opinions regarding activity in New York?
5

6 A I -- I don't recall that my opinions
7 changed from the original report to this report.

8 Q. Okay. Let's talk about how you took the
9 facts you received regarding New York and how you
10 got from those facts to your opinions in New York.

11 You were first given access to New York
12 documents on December 9th 2019, correct?

13 A I don't know if that was the exact date,
14 but it's within and around that timeframe, yes, sir.

15 Q. And just for precision, because I think
16 this matters, can we pull up Mr. Rafalski's
17 testimony from his deposition in this case, it's tab
18 2, February 7th 2020, at page 33.

19 And if you look up on the screen, sir --
20 actually, let's look at page 34, line 1 through 10,
21 where your answer finishes where in the middle of
22 the question I say, okay, and you say, I think when
23 the documents first come into me where I have
24 access, I believe it's around the 9th, but I'm not
25 positive, then I spent a lot more time looking at

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specific documents and policies, then once I was in the drafting I would be running back and forth between the draft and policies.

Was that consistent with your understanding that it was around December 9th that you first had access to New York documents?

A Yes, sir.

Q. And you completed your New York report -- you can take that down.

You completed your New York report on December 18th 2018, correct?

A Yes, sir.

Q. So that was nine to ten days after you got New York documents you completed your report containing new opinions on New York pharmacies and New York conduct and New York suspicious orders, correct?

A Yes, sir.

Q. And that limited time meant that you could not conduct a thorough review of the documents specific to New York and specific to this case, correct?

A I don't think that's an accurate statement. I reviewed -- I reviewed -- if you're

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1 talking specifically about the documents I cited, I
2 don't think that's an accurate statement. If you're
3 stating I had -- I reviewed all of the documents
4 involving the discovery, then I would agree with
5 that as an accurate statement.
6

7 Q. Well, let's talk about the Delta between
8 what you reviewed and what was produced and what you
9 had access to.

10 In your original Ohio report, you
11 reviewed about 2,500 documents, correct?

12 A I don't recall the exact number, sir.

13 Q. Do you take issue with that we've gone
14 through your list and counted it up; is your list
15 accurate, to the best of your knowledge? Do you
16 know?

17 A I believe my list is accurate, yes, sir.

18 Q. Then we counted about 1,500 additional
19 documents when you came over to New York.

20 Do you take any issue with that as a
21 factual matter?

22 A No, sir.

23 Q. In all of those documents that you
24 reviewed, they came from the Plaintiffs' lawyers,
25 correct?

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MS. CONROY: Objection, your Honor.

THE COURT: What's your objection?

MS. CONROY: It's foundation. It's not correct.

THE COURT: Mr. Rafalski, do you understand the question?

THE WITNESS: Yes, I think I understand the question.

THE COURT: If you understand the question, then answer it, go ahead. And if you don't understand the question, he'll rephrase it.

MR. SCHMIDT: Can I just say one thing? Miss Conroy literally answered the question for the witness. I don't think that's appropriate in an objection.

THE COURT: It doesn't matter. We're moving along. If you understand the question, answer it.

Go ahead.

A Yes. All the documents I received, I don't have any access to those documents, except through -- from the lawyers.

Q. You understand -- and I think you just

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told us this, but I want to be clear -- you understand that that 1,500 documents came from a much broader set of documents that have been produced by your lawyers in this case and by the Defendants in this case?

A Yes, I understand that.

Q. I want to just quickly touch on some of the documents you weren't given and then I'll touch on some of the ones you were given.

In terms of the documents you were not given, we see no documents from the two counties in this case on your list of materials reviewed, Nassau and Suffolk County. Do you take any issue with that?

A I don't take issue. I don't really have an opinion on that.

Q. Okay. Are you aware that over two million documents in total have been produced by all three Defendants in this case -- all three Plaintiffs in this case: New York State, Nassau County, Suffolk County, and you've reviewed less than 1,500 of those. Do you take any issue with that?

A I don't take issue with it. I really

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1 don't have any idea of how many documents to offer
2 an opinion on that, sir.

3 Q. Do you have any idea what's contained in
4 those documents that you were not given before you
5 reached your opinions from the State, from Nassau
6 County, from Suffolk County?

7 A No, sir.

8 Q. Just to link that up to your
9 methodology, you talk about conduct in your opinion
10 and controls against diversion, correct, and
11 compliance with the CSA?

12 A Yes, sir.

13 Q. You did not read any of the licensing
14 files that the State of New York generates for any
15 distributor or any pharmacy or any manufacturer in
16 this case, correct?

17 A Could you explain what you mean by
18 "licensing files"?

19 Q. Files generated in connection with
20 providing licenses to distributors or manufacturers
21 or pharmacies or their facilities.

22 A No, sir, I did not review those records.

23 Q. So you don't know if, in the context of
24 those documents, New York State, your client, made
25

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specific findings in the licensing context on the very questions you address, such as whether the distributors, manufacturers, pharmacies were, quote, able to maintain effective controls against diversion, true?

A That's a correct statement.

Q. You don't know whether your client, New York State, made specific findings in those licensing files on another issue you touched on, such as whether the distributors, manufacturers or pharmacies, quote, possess and operate a system to identify and report suspicious orders, correct? You don't know that?

A I'm not aware of any of that, correct, sir.

Q. Let me give you another example.

You talk about specific pharmacies in your report, correct?

A Yes, sir.

Q. You did not review any State or County investigative files on the New York pharmacies that you addressed, correct?

A That is correct.

Q. Would it be useful to know what kind of

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information they have, whether it's exculpatory or inculpatory, regarding those pharmacies?

A In forming my opinion I think all information is important and necessary. I wouldn't preclude any information, whether it be positive or negative.

Q. It would be useful to have that information from the investigative files if it exists for the pharmacies you looked at, correct?

A In a general term, yes. Would it be essential? I'm not sure I would agree with it being essential, but all information is important.

Q. Would you ever conduct an investigation of a distributor or pharmacy or a manufacturer without trying to make a determination of whether they had been previously subject to investigation when you were at the DEA?

A At the State and local level?

Q. At any level.

A At the federal level I would look at their history. It probably was a resolved matter so it wouldn't impact me -- it wouldn't -- you know, I don't think it would impact my opinion. I would look for similar conduct or I would integrate it

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into my investigation.

At the State level, I may look at those, but whether it would have to deal with a matter I'm looking at, it would be more of a conduct issue on whether they complied with regulations, their history.

Q. You didn't even determine for the pharmacies you looked at whether they are, to this day, right now as we sit here in our respective rooms and the folks in court sitting there in court, whether the State of New York and the DEA still licensed the pharmacies you looked at, correct? You didn't look at that?

A Generally, I would agree, but there was instances that I looked on the internet to try to see if I could find news articles or DEA releases where it might indicate there was adverse action. I didn't have the ability to -- at the DEA level I didn't have the ability to go in and do a licensed check or verification, so I didn't have a way to accomplish that.

Q. For the State you know they have a public website where you can go and look up whether any pharmacy is licensed. You didn't go look at

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that for the pharmacies you discussed, correct?

A I did not, sir.

Q. And you have not reviewed specific testimony from State and County employees regarding their standards for licensing pharmacies, licensing prescribers or investigating pharmacies and prescribers, correct?

A No, sir.

Q. Is what I said correct?

A Yeah, I just paused for a second, because I did review some testimony by the Director of the Bureau of Narcotic Enforcement, but I don't think I reviewed anything specific. I had to think about the categories you provided.

Q. Got it. Thank you for being precise, sir.

You talk in your report about some New York doctors and their prescriptions, correct?

A Yes, sir.

Q. New York has a prescription drug monitoring program called I-STOP that tracks prescription drug data in terms of specific doctors and specific prescriptions, correct?

A I'm aware of that, yes, sir.

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Q. And you didn't look at that, correct?

A I looked at some data that was dependent on the PMP. I'm sorry, the Prescription Monitoring Program's often referred to as a PMP. I saw some analysis of it, but I didn't look at the raw data from a PMP.

Q. Okay. You didn't go to PMP and do your own searches or do your own analysis, correct?

A I don't know that that was even possible, but I did not do that.

Q. You didn't read documents from the State and Counties talking about what they think are the actual causes of the opioid crisis outside of this litigation setting; did you?

A No, sir.

Q. Do you -- that's the Plaintiffs' side of the documents you didn't review. Now I want to talk about the defense side of the documents you didn't review.

Are you aware that the Defendants in this case produced well over a million documents in the New York litigation?

A I don't know the actual number, but that would not surprise me. Actually, I would probably

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say I would think that was low.

Q. And you recognize just from that number, and recognize that it's probably low, that your set of New York documents from the Defendants among that 1,500 are only a tiny, tiny fraction of what was produced, correct?

A Yes. But just for clarification, when I'm conducting my investigation I -- I don't need to see all of the documents. When I communicate there are certain types and categories of documents I need to review. If they were just to dump a million documents onto me, it would be much more difficult to focus my investigation and complete my methodologies, because I only need specific documents. I don't believe the whole one million is specific to formulating my opinion.

Q. Well, let's talk about what you've already told us in your direct examination was important to you in formulating your opinion.

You talked about needing to review diligence files; do you remember that?

A Yes, sir.

Q. The truth is you've not reviewed the entirety of the diligence files on New York

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pharmacies for any one distributor, correct?

A That is correct.

Q. You talked on direct about reviewing customers' files in the Masters investigation and how important that was to you, correct?

A Yes. But I -- hopefully, I was clear that I didn't review all of the customer files. I think I testified under direct that I reviewed a portion of them or a sampling that was significant for me to move forward on that case.

Q. You did not review all of the customer files for the pharmacies you talk about in your report, correct?

A That's correct. If customer files existed, I did a search for some of them to review and see what records I could find that are in my report. Some I did find some records. Some due diligence records. There are some I could find no records in.

Q. Okay. And that's searching in the subset of the documents the Plaintiffs' lawyers gave you, correct?

A Myself, yes, and then also I requested searches in relativity. So, hopefully, that

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encompasses all of the documents.

Q. When you flagged suspicious orders, you did not review all of the diligence on those orders, correct?

A Can you explain what you mean by that, sir?

Q. Yeah. Let me just try it.

You have an analysis in your report where you identify trigger orders, correct?

A Yes, sir. My schedule 2?

Q. Yes, sir. And my question is: Do you know if you reviewed all of the subsequent diligence on every one of those triggered orders?

A I did not.

Q. In terms of company emails, you did not purport to review all of the company emails regarding pharmacies in New York for the ten different Defendants you talk about, correct?

A It's my hope that through my request with Plaintiffs' attorneys that I was provided all the emails that were relevant to the topics. I don't have any way to be able to definitively say yes or no to that question, sir.

Q. You didn't review all of the company

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communications among those ten document -- those ten Defendants in the less than 1,500 documents you reviewed, all company communications regarding distribution and manufacturing and pharmacies in New York, correct?

A Same answer. I can't be absolute that I saw all the documents, no, sir.

Q. And you didn't review all of the transactional data for the ten Defendants in the State of New York, correct?

A Can you explain that?

Q. You talked about transactional data in your direct exam; do you remember that?

A Yes, sir. I think I testified I obtained it.

Q. Did you review it all?

A No, sir. Not every transaction, no, sir.

Q. So let's look --

MR. SCHMIDT: Can we put up, Mr. Reynolds, on the screen the slides that defense counsel -- Miss Conroy used with Mr. Rafalski, and let's go to Slide 9, please.

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Q. So bullet 2, collect Defendants' transactional data.

Do you know if that data was actually collected as opposed to ARCOS' data?

A Yes, I believe it was.

Q. Okay. And if it was, you did not review it all, correct?

A I did not review it all, no, sir.

Q. Put an X next to that one, please.

Let's look under compliance program, and let's go to the second bullet, due diligence, suspicious order monitoring and know your customer materials.

That's the diligence files we talked about in the customer files that you said you didn't review, and the diligence on all of the suspicious orders that you flagged that you didn't review, correct?

A That's correct.

Q. Put an X next to that one.

A Well, excuse me, could you ask that question one more time, please.

Q. That refers to diligence files that you said you didn't review in their entirety for any one

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distributor, customer files that you did not review in their entirety and diligence on every one of the triggered orders you identified, correct, that you did not review in its entirety?

A So I just want to make a clarification. In doing my methodology, there -- there -- I didn't sense --

Q. Can you answer my question, sir?

A I'm trying to, sir.

Q. Okay. My question is simply, this bullet refers to diligence files that you didn't review in their entirety, customer files that you didn't review in their entirety and subsequent diligence files on triggered orders that you identified that you didn't review in their entirety; true or false?

A So it's not a simple true and false answer. I think there are some instances where I looked at due diligence files, and I believe I looked at at least the totality of what I requested on certain customers. But if the question is if I looked at the whole universe of due diligence files, the answer to that would be no.

But at the same time, to formulate my

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opinion, it wasn't necessary to look at every document for all the due diligence.

Q. Let's just pick out that one example you just said. Just a simple yes or no question.

Did you review the customer files for all the pharmacies you talked about in the report?

A No.

Q. Did you review customer files, the subsequent diligence on every one of the triggered orders you report in your report?

A No, I did not.

Q. Thank you.

Investigators' interviews and witness statements, do you know if you read every bit of testimony from all ten Defendants against whom you give opinions?

A Not every word, no, sir.

Q. Not every deposition or interview either, right?

A I can't say that I didn't read portions of the ten or certain sections, but in completion to read them all, no, sir.

Q. Okay. Put an X next to that.

And then I asked you this just a moment

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ago, internal company communications and documents, you can't say that you reviewed all of those regarding New York pharmacies or regarding conduct in New York for the ten companies you looked at, correct?

A If you're asking absolute if I'm confident I read every document, the answer would be no, sir.

Q. Okay. Let's put an X next to that.

Let's go to the last one. Review of data resulting from metrics applied to data analysis; isn't that a reference to your Schedule 2 to your report?

A Yes, sir.

Q. And Schedule 2 contains the results of some analysis done by Dr. McCann, correct?

A That's correct.

Q. You did not yourself review the data that you used to perform those analyses, correct?

A Is the question -- so to clarify the question, are you asking if I looked at the actual transaction data instead, analyze?

Q. Yes, sir.

A I did not.

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Q. Okay. Let's put an X next to that one.

MR. SCHMIDT: And let's mark this as --
your Honor, are we starting again at Exhibit
A? Would that be okay?

COURT OFFICER: Judge, the last one was
A.

MR. SCHMIDT: I apologize if someone
answered that question. I didn't hear the
answer.

THE COURT OFFICER: Just say yes.

THE COURT: I said yes.

THE COURT OFFICER: I don't think he
heard you.

THE COURT: Yes.

MR. SCHMIDT: Thank you, your Honor.
Let's mark this as Defendant's Exhibit A to
Mr. Rafalski's testimony.

Q. I'm asking you about things you didn't
review. I want to switch over to things you did
review, if that's okay, the 1,500 documents that you
did review.

A Sure.

Q. Before I do, when you did your Masters'
investigation, did you put a lot of time into that?

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A Yes, sir.

Q. I think you said this on direct, you spent a lot of time reviewing documents and talking to people and reading testimony where it existed?

A I would probably say I would say no to that because moving forward there is some time constraints to turning in the Order to Show Cause. It can't linger forever. So there was a considerable amount of time, but each investigation is a little bit different.

Q. Okay. Would it be fair to say you spent hundreds -- you and your colleagues spent hundreds of hours gathering facts, looking at documents, talking to people at the company?

A Yes, sir.

Q. Would that be true for the Harvard matter you talked to as well, hundreds of hours looking at facts, looking at documents, talking to people, putting together information based on the facts you saw?

A Basically, I think that would be an accurate statement. It was less than Masters. It's hard, because at the time I'm employed as a DEA investigator and every minute is not spent doing

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that, but there is a considerable amount of time,
yes, sir.

Q. Let's talk about the 1,500 documents you
reviewed.

As I understood your direct-examination
testimony, those were documents you flagged as
important for you to review, correct?

A Well, I had asked for documents in
certain categories to cover certain topics, and
those would be the documents that were pulled in
those areas that are laid out in my methodology that
I could review in helping me draft a report.

Q. Well, is it accurate that the documents
you were asking for were what you thought were
relevant to your report?

A Yes, sir -- well, that I asked for and I
hoped they were relevant, yes, sir.

Q. But you're confident you did not read
every document they gave you, correct?

A As an absolute, I can't -- I don't want
to say that I read every document on that list, no,
sir.

Q. In fact, you are confident you haven't
read every document on that list, right?

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A I'm not sure, your Honor. I'm not sure.

Q. Let me see if I can help you out. Can we pull up again tab 2, the New York deposition, February 7th 2020, at page 49, please. I'm going to ask you about line 19 to 24, please. And if you want to just read the first two lines to yourself. The question actually starts on line 21, and I'll read it in just a moment.

I asked you in your deposition, Is it fair to say you have not read every document on Exhibit 8, which was your list of materials considered, the 1,500 you've been discussing.

Do you see that your answer is, quote, I'm confident that I didn't read every document in Exhibit 8; do you see that answer?

A I do.

Q. Were you testifying truthfully based on your knowledge then when you gave that answer?

A Yes, sir.

Q. Part of the reason you did not review all of the documents in the categories you told the lawyers were important or relevant for you to review is because you had relatively little time in that ten-day window between when you first got access to

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the documents and when you had to turn in your report, correct?

A I think that's a fair assessment, the volume of it, I agree.

Q. Do you remember telling me in your deposition that the upper limit of time you spent actually reviewing New York documents and preparing your report was about 13.5 hours? Do you remember testifying to that?

A I don't think I exactly testified to that. I think I testified that's what I billed. I think I may have testified, just off my memory, I probably put in time that I didn't bill, which was probably one of my weaknesses.

Extensive amount of time, but I'm sure that there was more than 13.5 just for -- I think that's how I testified at the previous deposition.

Q. Let's look at how you testified at the previous deposition, tab 2 again, the February 7th 2020 deposition at page 33, line 9, please, and if we can go down to 13 where your answer ends.

Fair enough. The upper limit on time reviewing New York documents for your report was about 13.5 hours.

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Do you see where your answer, I would say, yes, sir; do you see that?

A I do see that.

Q. Were you being truthful when you said yes, sir, the upper limit of your time was about 13.5 hours; were you being truthful in that testimony?

A I was truthful there, but I would like to add that I'm fairly certain that at some point during the 16 hours of deposition that I also answered that one of my weaknesses was my billing, and there was probably a little more time committed to the report than what was billed.

Q. And that 13.5 hours that you talk about here in your sworn testimony on the page, that is documents covering ten Defendants and their distinct activity in the State of New York, right?

A Yes, sir.

Q. It covers distinct manufacturer Defendants, distinct distributor Defendants, distinct pharmacy Defendants, correct?

A Yes, sir.

Q. And for a number of Defendants it covers a number of pharmacies they had some relationship

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with, correct?

A Yes, sir.

Q. It covers a range of doctors whose prescriptions were filled at those pharmacies, correct?

A Yes, sir.

Q. It covers that which you allege are thousands and thousands of flagged orders billed by some of those ten different Defendants, correct?

A Say that one more time, I'm sorry.

Q. Sure. That 13.5 hours that you testified about at your deposition as your upper limit, that covers what you allege are thousands and thousands and thousands of flagged orders that some of those Defendants filled, correct?

A I think the application of the metric identified those. I did not analyze -- I did not do the analysis, and I didn't review the specific orders, if that's what you're asking, sir.

Q. And your 13.5 hours upper limit covers testimony and interviews and documents from those ten Defendants and their witnesses in New York, right?

A Yes, sir.

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Q. You understand the testimony alone runs into the thousands of pages, correct?

A The deposition material?

Q. Yes, the deposition material.

A Yes, sir. New York examination, yes, sir.

Q. You would agree with me that you had limited time to prepare your report?

A I think in all these matters I wish I had unlimited amount of time, so, yes. Deadlines are always a limited amount of time.

Q. Okay. You never have enough time, but in this case it was a very short window to do this type of report, true?

A It was.

Q. You would have liked to have had more time, true?

A As I previously stated, on all of these matters I wished that I had -- with the volume of documents and the volume of material, I wish I had an unlimited amount of time but, unfortunately, I don't.

Q. Do you wish you had more time than 13.5 hours for this report in terms of the New York

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documents you were given and the millions you weren't given?

A I wish there was a longer deadline; yes, sir, I would agree with that.

Q. Would it be your generally accepted practice to write up your opinions before you have the facts?

A No, I wouldn't have any opinions.

Q. The truth is --

A If I can clarify that, though.

THE COURT: Yes.

Q. Yes.

A So I had -- I had opinions -- so this case and the work that I did isn't just encompassed in the 13-and-a-half hours. Much of the work started way back when I started on the MDL because much of the things that are documented in the New York report are hours that I spent when I was working on the MDL report, especially when it relates to all of the companies had policies, corporate policies in regards to due diligence and suspicious orders that are corporate-wide and they're utilized in all of the United States and all throughout the whole country. So just confirmation

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that there was nothing different in Ohio than there was in New York, let me move on on some of those topics.

So I know when we talked extensively about just the 13.5 hours, this, to me, is a cumulative investigation because it continues with the same companies, it just changes geographical locations.

Q. That's my question. We're focused on the 13.5 hours you spent looking specifically at New York facts.

A I understand, sir.

Q. Thank you.

The truth is, you actually started writing your New York report before you received documents regarding New York on December 9th, true?

A Well, I started working on a draft, but then part of that was, because some of the information was going to carry over, the corporate conduct by the companies, part of -- the initial part would be trying to identify and remove anything that was related to Cuyahoga and Summit County. So I think there was some drafting or work on the report before I received the documents.

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1 Q. Well, sir, you didn't remove everything
2 from your report related to Cuyahoga and Summit
3 County. There's a lot of information on your report
4 regarding Cuyahoga and Summit County, correct?
5

6 A Well --

7 Q. Is that true?

8 A Well, there is some in there, but it's
9 not that I failed to -- failed to remove it.
10 There's some in there that I left in there that it
11 was indicative of corporate conduct. I am aware of
12 one or two places where that it's specific, should
13 have been removed in my report today.

14 Q. You started writing your New York report
15 on December 1st 2019, correct?

16 A I think I testified previously that's
17 correct, that's when I put pen to paper.

18 Q. The only document you had at that time
19 when you put pen to paper on December 1st, the only
20 New York document that you had reviewed at that time
21 is the New York State Complaint against the
22 Defendants, correct?

23 A I think I had that in my possession. I
24 had much previous to that date, yes, sir.

25 Q. You didn't have any of the other

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categories of documents yet that we went through that were in -- that are specific to New York, right?

A I -- I don't have a direct recollection of exactly when I was provided those documents, sir.

Q. I think we covered it earlier, and I think it's reflected in your invoices, so I'll move on.

In terms of a Complaint, you understand that a Complaint is just the allegations from the lawyers, correct?

A Yes. I -- well, I think a Complaint is filed with the Court, and I think it's allegations that the State contends that they could prove in the legal matter, but, yes, sir, if that answers your question.

Q. I'm going to ask you, if you could, Mr. Rafalski, I'm trying to just ask yes, no questions. If you can answer just yes, no, as you did in your deposition, please do. I don't want to have to read your deposition testimony on every question, and I'll try to keep some of my questions to yes or no questions.

Do you understand that the Complaint --

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the allegations in the Complaint are one side of the story, the Plaintiffs' side of the story; yes or no?

A Yes.

Q. You understand that we have responses to those allegations as the Defendants?

A I think in all matters there's a response to a Complaint. As I testified, it's what the State or the federal government in their Complaint they intend to prove if the matter was to be adjudicated.

Q. So is that a "yes," sir? You understand we have responses to their Complaint?

A I'm not aware that you could formally respond to a Complaint.

Q. Okay. You've not reviewed our responses to the Complaint; true or false?

A I have not.

Q. Do you acknowledge that, picking up on something you were asked about on direct, the reason that you were able to prepare your 166-page report with specific opinions on New York so quickly in that ten-day window is because whether you knew it at the time or not, you ended up taking large parts of the Complaint and putting them word for word into

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your report? Are you aware of that now; yes or no?

A Well, when you ask that question, you -- you indicated whether I knew or not. I knew that that was in my report. It's not a situation where I did not know. It's just to clarify, because that's not a question I can say yes or no to.

Q. Okay. Let me try to ask it more precisely.

As you sit here right now, are you aware that the way you were able to prepare your report so quickly in that ten-day window is because large portions of that State Complaint ended up in your report word for word? Are you aware of that; yes or no?

A I don't want to argue about this. I don't really think it allowed me to complete my report. I think those things that were placed in my report are facts -- are primarily factual statements that are in support -- that support my opinion or the result of the conduct of the companies. I think my report, the opinions on my report stood, whether those facts are put in my report or not.

Q. Let me make it simpler, then I'll move on. See if you agree with me.

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Do you agree with me that large parts of your report are copied word for word from the Complaint; yes or no?

They're identical word for word to the Complaint; yes or no?

A That's a correct statement, I would say yes.

Q. You've had a chance to look at the Complaint, right, that's the document you got back on December 1st, right, in 2018?

A I believe I had it much earlier than that, but I acknowledge that I received it.

MR. SCHMIDT: Okay. And we'll go ahead and mark that, if we could, as Defendants Exhibit B, as in boy. And it should be in the binder in the package for my colleagues in court who very graciously passing out exhibits, it should be tab 6. Give the Court and Miss Conroy a copy, and I'll thank Miss Jones immensely on the record for helping me with that.

Q. While they are passing it out, I'm not going to ask you about text on it and, Miss Conroy, if you need me to stop before you have it, I'm going

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2 to ask general questions.

3 Am I correct that you had no role in
4 drafting the State's Complaint?

5 A That is a correct statement.

6 MR. SCHMIDT: Am I correct that -- can
7 we actually put it up on the screen, 6,
8 please.

9 Q. If you look up in the corner you can see
10 the date. It's small print, maybe even blow it up,
11 received March 28, 2019; do you see that?

12 A I can see that, yes, sir.

13 Q. You only became involved in this case in
14 November, correct?

15 A I believe November 13th, sir.

16 Q. Okay. So it was months and months and
17 months at least before you first saw this after it
18 was drafted, correct?

19 A I did not see this document until after
20 November 13th.

21 MR. SCHMIDT: May I ask that
22 demonstrative 2 from the box be passed out,
23 which I will mark for identification as
24 defense court Exhibit C, as in cat.

25 Q. And, Mr. Rafalski, while this is being

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1 passed out -- we can go ahead and put it on the
2 screen, just the cover -- did you review the motion
3 we filed regarding you in this case?
4

5 A Yes, sir.

6 Q. Did you see the attachment to it that
7 compared language taken from -- language that was
8 identical between your Complaint -- your report and
9 the State's Complaint, the State lawyer allegations?

10 A Are you speaking of the side by side
11 comparison?

12 Q. Yes, sir.

13 A I did.

14 Q. All right. So you've had a chance to
15 see this. We modified it slightly to include some
16 kind of draft numbers.

17 I'm going to go through this very, very
18 quickly, because it's quite long, and I don't want
19 to belabor it.

20 The slide pages are not numbered, but if
21 you flip to Slide 27, and we'll put it up on the
22 screen, it's the one that says McKesson. It's about
23 a third of the way in.

24 Do you see that on the screen, Mr.
25 Rafalski?

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A I see McKesson.

Q. You understand that this section of the document compares things you say about McKesson in your report to things that the lawyers had earlier said word for word in their allegations in the Complaint, right?

A Yes, sir.

Q. Let's look at Slide 28, the first of these. Do you see the language from your report on the right -- on the left, and the language from the Complaint on the right?

A I do.

Q. And you see that if you take out the first five words on the right from the State's Complaint, your language written in December 2019 is otherwise identical in this paragraph to what you saw in the Complaint, correct?

A Yes, sir.

Q. If you can go to the next slide, Slide 29, this one has a series -- has some text and a series of bullet points.

Do you see that your language in your report is identical to what the State had earlier drafted as their allegations in the Complaint, the

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2 lawyer allegations in the Complaint; do you see
3 that?

4 A I do.

5 Q. Now, one difference, the only
6 difference, do you see that you have added footnotes
7 that do not appear in that Complaint?

8 A Yes, sir.

9 Q. But the truth is those footnotes came
10 from the lawyers as well, correct?

11 A Yes. So when I would review this
12 document if it was a statement that I believe needed
13 to be supported by other information or other
14 documents I went back, and before I would accept
15 them I would ask for the footnotes, the information
16 that would provide this information or what
17 documents would provide these statements.

18 Q. And the lawyers wrote those for you,
19 correct?

20 A Wrote the footnotes?

21 Q. Yes, sir.

22 A They sent the material, the supporting
23 documents. They didn't write the footnotes.

24 Q. Okay. You didn't even have a chance to
25 verify all the footnotes, correct?

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2 A Well, that's another absolute. I know
3 that as they came in, I reviewed the footnotes and
4 compared them with the statements to make sure that
5 they actually said what they -- what the statements
6 said they said. So without saying that I did it for
7 everyone, because I want to leave that open in case
8 I missed one or two, I -- I did attempt to do -- to
9 verify each of the footnotes. I didn't just insert
10 them and move on.

11 Q. I'm going to show you your testimony for
12 the deposition. I think I'm now doing this for the
13 fifth time. If we look at your February 7, 2020
14 testimony, this time page 496, please.

15 And do you -- if you look at line 11, do
16 you see where you were asked the question: Did you
17 review all the footnotes, even the ones that
18 appeared for you? Do you see that question?

19 A I see it.

20 Q. Let me read that answer. "I don't
21 believe every one, because I ran out of time."

22 Did I read that correctly, sir?

23 A You did, but can I take one second, I'd
24 like to read my deposition prior and after.

25 Q. Sure. Let me just ask you a question as

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you look at that.

Were you being truthful when you gave that testimony, you don't believe you reviewed every one because you ran out of time; were you being truthful?

A Yes.

MR. SCHMIDT: Tell me when you're ready to move on.

In the meantime, can we put Exhibit C back up on the screen, Chris, it's demonstrative 2.

Thank you.

THE WITNESS: I've concluded reading my deposition.

MR. SCHMIDT: I don't think there's a question pending, Mr. Rafalski.

THE WITNESS: Pardon me?

MR. SCHMIDT: I don't think there's a question pending.

THE COURT: Mr. Rafalski, on redirect examination Miss Conroy, if she deems it appropriate, will go back to other portions of your deposition. I understand your request, but, if necessary, it will happen.

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2 Proceed, please.

3 THE WITNESS: Okay, your Honor. Thank
4 you. I'm sorry.

5 Q. Sir, go to the next slide, please, Slide
6 30.

7 Do you see you cut off the first
8 sentence of the Complaint on the right, but
9 otherwise your subsequent reports were word for word
10 identical to the lawyer allegations?

11 A Yes, sir.

12 Q. Next slide, 31, more word for word
13 copying from the lawyer allegations in the
14 Complaint?

15 A Is that a question, sir?

16 Q. Yes, sir.

17 A I agree, sir.

18 Q. Next slide, more word for word copying
19 from the lawyer allegations, correct?

20 A Yes, sir.

21 Q. In the interest of time, let's flip
22 ahead to Slide 44, please.

23 Do you see that this is language about
24 individual pharmacies in the State of New York?

25 A Yes, sir.

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2 Q. Again, you've combined two paragraphs
3 from the Complaint, but it's otherwise word for word
4 copying from the lawyer allegations in the
5 Complaint, correct?

6 A The language from both are the same, I
7 would agree.

8 Q. Okay. Jump two slides ahead to Slide
9 46. More allegations regarding specific New York
10 pharmacies; do you see that?

11 A I do.

12 Q. More word for word copying from the
13 Complaint, correct, on these New York specific
14 pharmacies?

15 A Here, let me just take a look, please.
16 Yes, I agree.

17 Q. There are a number of other slides in
18 the section, I won't go through, where you, again,
19 have paragraphs on McKesson that are word for word
20 copied on the Complaint lawyer allegations, correct?

21 A I have reviewed your filing. I will
22 agree there are more, yes, sir.

23 Q. Go back to Slide 2, please. I just want
24 to establish for the record this is the ABDC section
25 or the AmerisourceBergan section.

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If you go to Slide 3, you've removed the word NYCSA from the Complaint and replaced it with the word CSA, otherwise copied from the ABDC section, correct?

A Yes, sir.

Q. Slide 4, more word for word copying from the lawyer allegations in the Complaint?

A May I make a statement about the last one? We don't need to go back, but I think there were footnotes added to that also.

Q. Okay. And we talked about the footnotes.

If we go to Slide 4, more word for word copying from the lawyer allegations in the Complaint in terms of ABDC allegations, correct?

A With the inclusion of footnotes supporting the statements, yes, sir.

Q. But the material came from the lawyers, correct?

A Footnotes provided to me that I reviewed from the lawyers, yes, sir.

Q. Slide 5, same thing, more word for word copying from the allegations from the lawyers in the Complaint into your report regarding ABDC; do you

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see that?

A With the inclusion of a footnote with citing a supporting document, yes, sir.

Q. In the interest of time I'm not going to go through the pages and pages and pages and pages where this happens with ABDC, but you see it goes on and on for ABDC, correct?

A Well, I've reviewed the submission that you made on this matter, but I just -- if there are footnotes which showed a review and a request for verification documents, I'm not asking you that we go through every one, but I think that at least there's some acknowledgment that although the content was copied and pasted, there was a review necessary to review -- to require those supporting documents.

THE COURT: Mr. Rafalski, with the exception of the footnotes, the answer is yes?

THE WITNESS: That is correct, your Honor.

THE COURT: Next question.

MR. SCHMIDT: Thank you for that help, your Honor.

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Q. Slide 48 is the Mallinckrodt section,
and if we can go to Slide 49, please.

Do you see that with the exception of
changing the beginning of the section, again, word
for word copied from the Complaint with the
exception of footnotes the lawyers gave you?

A Yes, sir.

Q. Same for Slide 50, correct?

A Your statement on the previous is the
same, the answer would be yes.

Q. Same for Slide 51, correct, you combined
two paragraphs into one but otherwise -- you add the
footnote from the lawyers but otherwise word for
word copying from the Complaint, correct?

A Well, I would say yes to the word for
word copying.

Q. And that goes on and on, I don't have to
go through every one, correct? You know there are
many instances of this for Mallinckrodt, correct?

A There are.

Q. And then, finally, if we go to Cardinal
on Slide 56, do you see this is the Cardinal
section; do you see that, sir?

A I see Cardinal. I'm sorry, yes.

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Q. That's not the question.

A Okay. I thought something else was coming up, so I'm sorry.

Q. Something is coming.

If you look at the next -- actually, let's look at Slide 58.

Do you see that you have a series of bullet points, and you changed the preamble a bit, but with the exception of providing footnotes, the attorneys gave you word for word identical in the bullet points?

A Just a statement, I hope this doesn't anger the Judge.

Q. Well, can you answer the question?

A Yes. But the way you phrased the footnotes is -- yes, the answer is yes.

Q. Okay. And then let's turn to Slide 61.

Again, you've changed the preamble a bit, added footnotes that you were given, otherwise word for word copied from the Complaint, correct?

A Yes.

Q. There are many other examples of that for Cardinal, correct?

A Yes, there are.

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Q. Now, you said you had a chance to review this filing, and I'm going to ask you a question that I asked you at your deposition.

Do you take issue with the fact that all of your discussions in your Complaint about New York customers of McKesson, Cardinal and ABDC was copied word for word from the Complaint; do you take issue with that?

A I'm going to try to answer that consistently with the way I answered it previously. My exception was is that I wasn't told that it was taken from the Complaint and --

Q. Okay. But you now know that it was, correct? Everything you say about specifically New York pharmacies was taken word for word from the Complaint, correct?

A I knew that the day of the deposition, yes, sir.

Q. You know that much of what you say about Mallinckrodt customers in New York was pasted from the State's Complaint, whether you knew that at the time or not?

A I was provided material from the State and I reviewed it and inserted in my report. I just

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1
2 didn't know that it was taken verbatim from the
3 Complaint. Does that answer your question?

4 Q. Yes.

5 As to Mallinckrodt now, you know that it
6 is taken verbatim from the Complaint?

7 A I did. I knew that the day from the
8 first deposition.

9 Q. Is there any pharmacy you recall reading
10 about in the Complaint that you said I can't give an
11 opinion on this pharmacy?

12 A No, I don't recall ever having that
13 occur.

14 Q. There's no pharmacy in your report that
15 doesn't also appear in your Complaint, no New York
16 pharmacy, correct? You understand?

17 A I don't know, sir.

18 Q. Okay. Is there any allegation in the
19 Complaint that you saw the lawyers make that you
20 said, I can't copy this into my report, that you
21 could point us to sitting here right now?

22 A No. I think all of the statements that
23 the -- that were made in those, all the material
24 that I adopted I think were consistent with my
25 opinions. I don't think conflicted with my

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opinions, no, sir.

Q. Now, you compared this report, Plaintiff's Exhibit 1, your New York report, you compared it to reports you prepared or work you did while you were at the DEA, correct?

Do you remember doing that?

A I don't know. I don't understand the question, sir.

Q. Sure. I thought, and I might have misunderstood, so if I misunderstood tell me if I misunderstood, but I thought I heard you on direct exam say, may be a comparison between the way you did your report in this case and the way you did reports when you were working at the DEA; did I hear that correctly?

A My methodology, the report wasn't in the same form or format. I hope I understand your question correctly, but the methodology to get to forming my opinions or to completing my investigation was the same.

Q. Were your reports from the DEA ever written to you by private lawyers bringing a civil lawsuit?

A No.

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2 Q. Is that generally accepted practice of
3 the DEA to have the reports you did and
4 investigations be written by private lawyers
5 bringing a civil lawsuit?

6 A No, sir.

7 Q. You talked briefly, I think if I heard
8 you right, about visiting McKesson in ABDC
9 facilities; did I hear that correctly?

10 A You did.

11 Q. That's not something you did in your
12 report, that's something you did when you were at
13 DEA, correct?

14 A In regards to this litigation?

15 Q. You didn't visit McKesson or ABDC
16 facility with your work here, you did that when you
17 were with DEA, correct?

18 A Yeah. When I answered the question I
19 wasn't -- wasn't in my DEA capacity, but the
20 question was was I ever in the facility, and the
21 answer was yes. It was not in regards to this
22 litigation.

23 Q. You said you applied the same
24 methodology that you did in your DEA work; is that
25 correct?

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A I -- yes, sir. I drew my methodology in this report from my experience, training and case investigations while I was at the DEA. Methodology.

Q. When you were at the DEA, you never found violations at a distribution center for McKesson or a distribution center for ABDC, correct?

A That's correct.

Q. Well, for that matter, Cardinal, correct?

A That's correct.

Q. You never told anyone at ABDC or Cardinal or McKesson that you saw violations, correct?

A That's a correct statement, yes, sir.

Q. Do you know you -- I don't know if I have it precisely right, do you know that you worked pretty closely to a McKesson distribution center, Laconia, correct?

A Yes, sir.

Q. I'm going to ask just a couple more follow-up questions on this issue and then I'll move to another topic.

Do you still have your report in front of you?

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A I do.

Q. Look with me, if you would. I want to focus on some of the opinions you offer in your report.

Look with me, if you would, at page 78 of your report. If we could put that up on the screen, please. I think the reference, for your purposes, will be tab 1.

A And it was page -- oh, you got it there, thank you.

Q. I want to focus just on that first sentence regarding ABDC.

Your report said Amerisource compliance policies are flawed from initial mid-customer onboarding; do you see that?

A Yes, sir.

Q. That's an opinion you offer, correct?

Mr. Rafalski, I don't know if you heard my question. Is that an opinion you offer?

A Yes, sir.

Q. Do you know that that opinion came word for word from the lawyer allegations in the Complaint?

A I don't recall if it did or not, sir.

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Q. Okay. I can show it to you, if you want.

A I don't dispute it. If you say it, I acknowledge it.

Q. Okay. Let's look at page 62 of your report.

At the top of page 62 you say McKesson CSMP's were riddled with flaws and loopholes that rendered them substantially ineffective; do you see that language?

A I do, sir.

Q. Is that an opinion you offer regarding McKesson in this case?

A Yes, sir. I think that's accurate to my review of documents and materials and my investigation of this case, yes, sir.

Q. Are you aware that that opinion comes word for word of the lawyer allegations in the Complaint that were given to you?

A I'm not aware of that, but it's consistent with my opinions on the matter.

Q. Okay. You take issue with that? Should I show you the Complaint?

A I do not take issue with that.

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Q. Page 66. Two more of these.

You state on page 66, right at the top, McKesson system for identifying and reporting suspicious orders; do you see that sentence?

A Yes.

Q. Inadequate to inscrutable, pretty colorful language; do you see that?

A I do.

Q. That's an opinion that you offer regarding McKesson?

A Yes. I believe it's consistent with my other opinions, yes, sir.

Q. Do you take issue with the fact that that opinion came word for word from the State Complaint, the lawyer allegations in the State Complaint?

A No, sir.

Q. Last one, page 141, please.

THE COURT: Is there a hardcopy of this document that I can have?

MS. CONROY: Your Honor, I think you have it. It was an exhibit marked for identification, Number 1, Mr. Rafalski's expert report, but I can get you another one.

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MR. SCHMIDT: It's tab 1 in the response, if that helps.

MS. CONROY: I think 1 is being passed up.

MR. SCHMIDT: Thank you.

THE COURT: What page did you just refer to?

MR. SCHMIDT: The last page. Let me just quickly go through it for your Honor. The first page I covered was page 78.

THE COURT: And the last page you mentioned was what?

MR. SCHMIDT: Was page 66. That's with colorful language about being inadequate to inscrutable.

THE COURT: Okay. Go ahead.

Q. Last one I'm going to do on the opinions, Mr. Rafalski, is -- can we go to page 151.

A 151, I'm sorry?

Q. I'm sorry, 141.

A Okay.

Q. 141.

I just want to confirm that I have the right page. Yeah, it's about partway down,

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paragraph 6; do you see that?

A Yes, sir.

Q. Which is: Mallinckrodt did not stop shipments they knew were destined to New York that were lightly engaged in diversion; do you see that?

A Yes, sir.

Q. That's another one of your opinions regarding Mallinckrodt, correct?

A Yes, sir.

Q. Do you take issue that that comes word for word from the lawyer allegations in the Complaint?

A I do not.

Q. Now, you've recognized that as an expert you're supposed to base your opinions on facts and not advocate for one side or the other, correct?

A Yes, sir, I understand that.

Q. You agree it would be improper for an expert to be biased for one side or the other when giving his opinion, correct?

A Yes, sir.

Q. We've now seen how large portions of your report are word for word identical to the lawyer allegations in the Complaint, correct?

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A Yes, sir.

Q. And as best you know, you did that without seeing our side of the story on that in terms of what our response was to that, correct?

A In response to the Complaint, the New York Complaint?

Q. Yes, sir.

A I did not review the New York Complaint, no, sir.

Q. You did not review our response to that, our side of the story, correct?

A Yes, sir, that's what I meant.

Q. You understand that your report is supposed to be your own words, not the words of your lawyers, right?

A Yes, sir.

Q. Do you recall telling me, and I kind of harped on this with that language about that inscrutable to incomprehensible or whatever it was, do you recall telling me in your deposition that some of the words in your report were not typical words you would use? Do you remember telling me that?

A Yes, sir.

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1
2 Q. Do you remember telling me that if you
3 had more time to work on your report, it would have
4 been more in your voice?

5 A I don't remember that exact statement,
6 sir.

7 Q. Let's take a look then.

8 A Part of my deposition?

9 Q. Yes, sir.

10 MR. SCHMIDT: Can we pull that up, I
11 think it's tab 2, at page 88, please, 11
12 through 14. Can we put that up on the
13 screen, please. The February 7th New York
14 deposition.

15 Q. Do you see where you were asked if you
16 had more time to work on Exhibit 1, it would be more
17 in your voice, correct? And you answered, Yes.

18 Was that truthful testimony?

19 A I acknowledge that I answered yes, as
20 you indicated here. If I could just take one
21 minute, I would like to read it a little more before
22 and after that statement.

23 Q. The only question we're looking at, Mr.
24 Rafalski, were you being truthful when you said,
25 Yes, if you had more time it would be more in your

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voice; were you being truthful in that testimony?

A Generally, yes, unless some of the questions before or after either conflict or modify that statement. I don't want to take a lot of the Court's time. I just want a quick minute to look.

Q. My next question.

A Okay, I'm good. We can move on. Thank you.

Q. Thank you.

You would agree with me that it would be improper to just be a mouth piece for the lawyers and say whatever it is that they want you to say, correct?

A Yes, sir.

Q. You agree that it would be wrong to simply have someone else write your report for you and adopt it word for word, correct?

THE COURT: Time out. My screen went blank. Anyone else's?

MR. SCHMIDT: I think it's because you just pulled down the document.

THE COURT: That's fine.

Q. Sir, I ask you -- can you hear me, Mr. Rafalski?

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A I can hear you.

Q. Do you agree with me that it would not be proper to simply have someone else write your report for you and adopt it word for word; do you agree with that?

A Yes, I agree with that.

Q. It would be improper to take passages that the lawyers gave you for your report and simply adopt them verbatim, correct?

A Without reviewing them and the supporting documents and adopting it as my own, yes, just to merely take them and put them into my report, I would agree with that.

Q. That would be improper, correct?

A That would be improper.

Q. In this case, we've now been through the fact that very important passages of your report are the identical verbatim words that the lawyers put in their Complaint, which was written close to a year before you wrote your report, correct?

A With the caveat that there were footnotes added to support those statements.

Q. It's not your generally accepted practice to simply take lawyer allegations and adopt

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2 them as your own; is it?

3 A It is not.

4 Q. It's not your generally accepted
5 practice to simply cut and paste lawyer allegations
6 and adopt them as your own, correct?

7 A That is correct.

8 MR. SCHMIDT: Okay. I'm going to shift
9 gears now and ask you about another topic.
10 I'm through with that topic.

11 Your Honor, I don't know if you want to
12 take a break in the afternoon, I'll keep
13 going if your Honor is good.

14 THE COURT: We'll take ten minutes. Ten
15 minutes, everybody.

16 (WHEREUPON, a short recess was taken.)

17 THE COURT: Okay. Is everybody back?

18 You may proceed, Mr. Schmidt.

19 MR. SCHMIDT: Thank you, your Honor.

20 Q. One more question on the subject I
21 forgot to ask you that we were talking about.

22 A section of the report that you carried
23 over from the Ohio case, do you know if all of that
24 was written by you as opposed to being written by
25 lawyers in the first instance?

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MS. CONROY: Objection, your Honor.

THE COURT: What's your objection?

MS. CONROY: Objection, your Honor. I believe that there are orders in place in the MDL about the drafting of expert reports and what can be inquired about the expert reports.

THE COURT: There are parameters?

MS. CONROY: That's correct, your Honor.

THE COURT: Are you speaking of the order, the decision?

MS. CONROY: I was actually speaking about some of the pretrial orders with respect to the expert reports. It may, in fact, be in an order as well. The protocols that we are following and whether or not either side could inquire about the drafting of an expert report.

So it's one thing to talk about the drafting of the report in your orders, your Honor, concerning this expert report in New York, but now if we're going to get into the drafting of an expert report in the MDL, that's something different.

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THE COURT: Okay. Mr. Schmidt, are you out of bounds?

MR. SCHMIDT: There is such an order in Ohio. I think it's a different universe when the report gets incorporated into New York, but I'll move on. I think it's evident from the report. I'll move on.

THE COURT: Thank you.

Q. Mr. Rafalski, one of the things the Court talked about in setting up these hearings was the question of causation, and I want to spend a few minutes in the next section of time I have with you talking about how your opinions fit into causation and to do that I want to ask you some questions about the pharmaceutical distribution chain, okay?

A Yes, sir.

Q. Before I do that, I just want to ask some questions about why we have prescription opioids. You agree they serve an important medical purpose, correct?

A I do.

Q. In fact, when we had the chance to ask you that in your deposition, you said, Absolutely, they serve an important medical purpose, correct?

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1
2 A My employment with the DEA division was
3 to ensure the uninterrupted supply to those people
4 who need those drugs, so absolutely I agree with
5 that.

6 Q. And you anticipated my next question.

7 That's a coordination of the DEA to
8 ensure uninterrupted supply of prescription opioids,
9 correct?

10 A That's the major part of the mission
11 statement for diversion, yes, sir.

12 Q. Okay. So let's talk about how that
13 access to prescription opioids is maintained in our
14 country, and I'm going to put up on the screen, it's
15 in the box as demonstrative Exhibit 3.

16 If we could pass that out and put that
17 on the screen, and if Miss Conroy would like this or
18 if you would like this, Mr. Rafalski, I can show you
19 where this comes from, but you may remember this,
20 it's from a 2020 government watchdog report from the
21 GAO; do you remember seeing this in your deposition?

22 A I don't see anything yet on the screen.
23 I remember the discussion at my deposition.

24 THE COURT: Wait until you see something
25 on the screen.

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A Yes, I recall this.

THE COURT: Okay.

Q. You recall this image, this figure coming from a GAO government watchdog report on the DEA, correct?

A Yes, sir.

Q. Let's just breakdown what we're looking at here.

In the middle on the right -- and, Chris, I don't know if there's a way to circle the box or something, but we see patients.

Do you see that at the end of the middle row of blue items? Do you see that?

A I see it, sir.

Q. Okay. And if we go back out, Chris, and let's just circle them, let's not blow them up. Patients, of course, as this image shows, get their prescriptions from healthcare professionals, including doctors, which you see above; do you see that?

A I do. I can read it without blowing it up, if that helps save time for you.

Q. That helps save an immense amount of time, thank you.

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And then when they get that prescription from their doctor, they take it to the pharmacy to have the prescription dispensed, and we see the pharmacy to the left of the patient, correct?

A Yes, sir.

Q. The pharmacy, in turn, gets the prescription medication from the distributor, which is the next one over; do you see that?

A Yes, sir.

Q. The distributor, in turn, gets it from the manufacturer, correct?

A Yes, sir. That's generally how it works.

Q. Okay. And I want to break this down a little bit more and ask you about some of these entities. Let's start with doctors. The ones who write the prescriptions.

Doctors are only supposed to write prescription -- opioid prescriptions in response to patient medical needs, true?

A That's one aspect. The other one would be a doctor/patient -- the existence of a doctor/patient relationship.

Q. Okay. So let me see if I have it right.

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Doctors are only supposed to write prescription opioids if they have a doctor/patient relationship and make a judgment about a medical need, correct?

A Yes. That's not the exact language, but I accept that, yes, sir.

Q. Pharmacies, in turn, can only dispense a prescription opioid in response to getting a prescription from a healthcare professional given to a patient, correct?

A Generally I agree with that, yes.

Q. And that rule applies no matter how many prescription opioids a manufacturer makes or a distributor distributes, the pharmacy is only supposed to dispense the prescription opioid if they get a prescription from a healthcare professional, correct?

A Yes. Just in the previous question I kind of couched my answer. The pharmacy just doesn't fill it. They're supposed to evaluate it, but other than that, I agree with your statement.

Q. Okay. So just to go back. Pharmacy can't dispense a prescription opioid without having a prescription in hand from a licensed healthcare

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professional and properly evaluating it, correct?

A Correct.

Q. And that statement is true no matter how many prescription opioids a manufacturer makes or how many prescription opioids a distributor distributes, correct?

A Yes, sir.

Q. In terms of looking at how many pills get dispensed by pharmacies, that's directed by the number of pharmacies -- by the number of prescriptions that get written, correct?

A No, I don't -- I don't agree with that statement.

Q. Okay. Do you know of any prescription opioids that have been dispensed by a New York pharmacy made by a manufacturer in this case or distributed by a distributor in this case that were dispensed without a prescription being written for them?

A No, I do not.

Q. Is it the case that every prescription opioid that is dispensed by a pharmacy is supposed to be dispensed in response to a prescription written by a healthcare professional?

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A Yes, sir.

Q. Okay. And what is supposed to guide the number of prescriptions that get dispensed by pharmacies is how many prescriptions physicians write or other healthcare professionals write, correct?

A Can you repeat that one more time, sir?

Q. Sure. What is supposed to guide the number of prescriptions that get dispensed by a pharmacy is the number of prescriptions that get written by healthcare professionals exercising their obligation to their patients, true?

A Just the word "guide," I don't know if it guides. Just the number of pills that are dispensed by a pharmacy are dependent on legitimate prescriptions from practitioners, not guiding, I just don't like the word guiding statement. Other than that, I agree with it.

Q. You said it better than me.

The number of pills that a pharmacy dispenses are directed by the number of prescriptions written by healthcare professionals, correct?

A That's correct.

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1 Q. If we look at the bottom of this graph,
2 the green box down at the bottom, you recognize that
3 those are different types of diversion that can
4 occur?
5

6 A Yes, sir.

7 Q. Specifically some of them are types of
8 diversion that can occur from manufacturers and
9 distributors, correct?

10 A Yes, sir. I don't know that this list
11 is inclusive of all methods of diversion, but I do
12 agree that what's stated here is diversion.

13 Q. You don't talk in your report about any
14 instances of diversion from manufacturers or
15 distributors that occurred while they actually have
16 the prescription opioids when they go to a pharmacy,
17 correct?

18 A I do not.

19 Q. You're aware that throughout the opioid
20 crisis doctors steadily increased the number of
21 prescriptions that they were writing for
22 prescription opioids?

23 A Yes, I'm aware of that.

24 Q. Do you know when that peaked?

25 A Well, that's a general statement and

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there are many drugs. If we're talking about specifically the opioids, the Oxycodone and hydrocodone, I would say sometime around between the very end of 2011 and mid 2012 for -- and that's not an absolute statement but, generally, I would say that you're going to see the peak somewhere within that range.

Q. Do you give any opinion in this case about whether doctors, medical professionals, by writing prescriptions for prescription opioids and by increasing their volume of prescriptions helped cause or contribute to the opioid crisis? Do you give such an opinion in this case?

A I do not. And I was not tasked to research that matter or opine on it.

Q. You don't address the causal role of the medical profession in the opioid crisis, correct?

A No, sir, I do not.

Q. Look back at figure 1 up at the top, it's got another one of those green diversion boxes, right front and center at the top for doctors who write prescriptions improperly; do you see that?

A Yes, sir.

Q. You understand that those are sometimes

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referred to as pill mill doctors, correct?

A That's one of the nicknames they give to them.

Q. And you would say pill mill doctors were definitely a causation of the opioid crisis, correct?

A I would say doctors that were writing outside of a legitimate medical patient relationship and absolutely no medical need would be one of the causation factors.

Q. You haven't addressed the role of pill mill doctors in your report or in your opinions in terms of causing the opioid crisis, correct?

A Same response before. I was not tasked as an expert to evaluate that and provide an opinion on that matter.

Q. You can't quantify how much responsibility they bear for the opioid crisis, correct?

A Again, the same answer. I didn't research the matter and provide any opinion on that, so I really have no response to that question.

Q. Okay. You have no quantification for pill mill doctors, 90 percent responsible, 4 percent

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responsible, somewhere in between, correct?

A No, I have no idea on a percentage. I have no response to that.

Q. Okay. On the right side of this graph there are instances of patient diversion; do you see that?

A Yes, sir.

Q. The top box refers to something called doctor shoppers; are you familiar with that?

A Oh, yes, sir.

Q. And then below that it refers to patients who can provide legitimately maintained drugs to friends and family for free?

A Yes, sir.

Q. Have you sometimes heard that referred to as diversion from the medical cabinet?

A Yeah. I don't really agree that that is diversion. I think medicine cabinet diversion usually happens without the consent or knowledge of patients, but I don't disagree with that statement here.

Q. Okay.

A Not to qualify it as medicine cabinet diversion.

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1
2 Q. When a patient misuses medication that
3 was prescribed for a legitimate medical purpose,
4 whether it's giving it away or selling it, who's
5 responsible for that?

6 A The end user, the patient.

7 Q. When someone steals medication, what you
8 call diversion from the medical cabinet, from a
9 patient who got it by legitimate -- for legitimate
10 medical needs, who's responsible for that
11 wrongdoing?

12 A I don't think -- as long as they were
13 safely stored, I don't know that there is a person
14 who is responsible for that causation.

15 Q. Not the person who stole it?

16 A Well, they would be responsible, but
17 that's a result of their actions. I don't think
18 they are the causation. I guess maybe I'm just not
19 agreeing with the actual words.

20 Q. Okay. You agree that doctor shopping,
21 giving drugs away for free, selling them as part of
22 a criminal enterprise is a potential crime?

23 A I think it is a crime, yes, sir.

24 Q. None of those activities involve
25 distributors, correct?

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A Not directly, sir.

Q. Okay. This is an important one, so I want to go back to your testimony for this to be very precise. February 7th 2020, let's go to page 319.

A If we're going to my statements on diversion, I'm aware that I had some thoughts on that after my testimony.

Q. Okay. Sir, let me just show you your testimony and then --

A Sure.

Q. -- if Miss Conroy wants to ask you questions, she can.

If you look at the bottom of 319, do you see where I ask you some of those similar questions about patient diversion and -- you don't need to put it all up. Do you have it in front of you, Mr. Rafalski?

A I see it.

Q. Okay. Do you see where I ask you some similar questions about these different types of diversion being criminal activity?

And why don't we just show -- if we're going to show it, Chris, why don't we show from line

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13 to line 24.

THE COURT: Can I see the complete answer, please.

MR. SCHMIDT: Yes, of course. Let's show it from 13 to 24. This is more really just a setup for what I'm going to show you is impeachment testimony.

THE COURT: Only because I thought there was more.

MR. SCHMIDT: It carries over to the next page, and I will show what's on the next page, your Honor. So this orients us to what we're talking about here.

Q. Do you see that I ask you that all three of those activities occur and then we define what we're talking about posing as legitimate patients to give drugs to a family member for free, and, I'm sorry, what's the third one, selling, and I say selling them is part of a criminal enterprise.

And you say, I think all three have the potential -- have a potential to -- and then if we carry over to the next page -- to have criminal actions, yes, sir.

Do you see that?

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2 A I do.

3 Q. Okay. I just did that as a table
4 setting. This is the question I wanted to ask you.

5 Do you see where I then immediately
6 asked you, and none of those involved distributors,
7 correct?

8 A I see where it says that, yes, sir.

9 Q. Do you see your answer, That's correct?

10 A Yes, sir.

11 Q. Were you being truthful, as best you
12 could, at that time?

13 A I was.

14 Q. Okay. None of them involve
15 manufacturers, correct?

16 A That's how I answered at that time.

17 Q. Were you being truthful?

18 A At that time, yes, sir.

19 Q. None of them involved pharmacies,
20 correct?

21 A I don't -- do I have an answer to that?

22 Q. I didn't ask you that question.

23 Do any of them involve pharmacies, sir?

24 A I don't agree with that.

25 Q. If a patient steals something from a

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1
2 medicine cabinet, does that involve a pharmacy?

3 A That specific example, no.

4 Q. If a patient gets a legitimate
5 prescription from a pharmacy, then turns around and
6 sells it for money, does that involve a pharmacy,
7 sir?

8 A No. Just for clarification, we talked
9 about doctor shoppers and pill mills and a lot of
10 other circumstances, so that's why I'm just cautious
11 in answering. Specific examples like that, I could
12 say no.

13 Q. If a patient gets a legitimate medical
14 prescription for opioids and gives them away for
15 free, does that involve the pharmacy?

16 A No, sir.

17 Q. You don't give an opinion in your report
18 or in your testimony about whether --

19 MR. SCHMIDT: Let's go back to the
20 demonstrative number 2, if we could, please,
21 Mr. Reynolds. I'm sorry, demonstrative
22 number 3.

23 Q. You don't give an opinion in your report
24 about the role that individual diversion of the type
25 we've been talking about played in causing the

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opioid crisis, correct?

A Can you say that one more time, I'm
sorry?

Q. Yeah, of course.

You don't give an opinion in your report
about whether individual diversion, including like
the type we've been talking about, caused or
contributed to the opioid crisis, and, if so, how
much, correct?

A That is not contained within my opinion.
I was not asked to research and opine on that.

MR. SCHMIDT: Okay. Let's go ahead and
mark this for identification as Court's
Exhibit -- as Defendant's Exhibit, I think
we're up to D, as in dog.

Q. Have you seen data indicating that 70 to
80 percent of diversion starts in the medicine
cabinet at home, sir?

A I do recall that previous question, and
I recall my previous testimony in that manner.

Q. You've seen such data, correct?

A Yes, sir.

Q. Let's just show the Judge what we're
talking about. If I could ask my colleagues in

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2 court to pass out tab 25, and we'll mark it as
3 Exhibit E, as in excellent.

4 Do you remember being shown this
5 document at the Suffolk County Supreme Court Special
6 Grand Jury for the first time at your deposition?

7 A I do not.

8 Q. Okay. Do you recall that you had not
9 seen this document until I showed it to you?

10 A I do not. Is it possible to see that
11 statement in my deposition?

12 Q. Of course. Of course. February 7, 2020
13 deposition, tab 2, at page 306, please.

14 A 306?

15 Q. Yes, please. And if we look at 19 --

16 MR. SCHMIDT: And, Mr. Reynolds, if
17 there's a way, following up on the Judge's
18 question earlier, to put the continued answer
19 on the next page so we can see it all.

20 Nicely done.

21 Q. The question on 19 is: I'm giving you a
22 copy of what I've marked as Exhibit 19. This is a
23 document that says Suffolk County Supreme Court
24 Special Grand Jury, dated April 17th, 2012, and it's
25 titled Grand Jury Report, and it's 99 pages. Have

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you seen this document before today?

You answered: No, sir.

A I see that. I have my copy of my deposition. I acknowledge that's what it says, sir.

Q. That was the testimony?

A Yes, sir.

Q. If you can just orient us as to what this is. Do you see on the cover of Exhibit E, it states the Suffolk County Supreme Court Special Grand Jury Term 180 was impaneled on January 4th, 2012, by order of the Honorable James C. Hudson, to complete an investigation into the diversion and dissemination of controlled substances and issues related thereto; do you see that?

A Yes, sir.

Q. If we flip ahead to page 20 of this document, do you see that there's a heading, it says, The Medicine Cabinet?

A I do.

Q. Below that it says: Experts estimate that 70 to 80 percent of diversion starts in the medicine cabinet at home; do you see that?

A Yes, sir.

Q. And that's the type of diversion that we

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1 talked about a few minutes ago, it has nothing to do
2 with distributors, manufacturers or pharmacists,
3 correct?
4

5 A Yes, sir.

6 Q. If you look at the footnote, we've
7 talked about footnotes a little bit, this footnote
8 cites the Federal Substance Abuse and Mental Health
9 Services Administration; do you see that?

10 A Yes, sir.

11 Q. Have you reviewed that federal data?

12 A No, sir.

13 Q. Okay. Have you seen the 70 to 80
14 percent statistic regarding diversion starting in
15 the medicine cabinet at home; have you seen that in
16 other sources?

17 A I know it's been discussed previously.
18 I believe in this document that it appears again.
19 But the second time it appears in the document I
20 believe it applies to children. And I remember this
21 document from my first testimony. I did not agree
22 with the 70 and 80 percent of diversion.

23 Again, I also didn't agree with the
24 later statement because I didn't ask -- I didn't
25 hear the word children. If you insert the word

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children, my errata that I filed in regards to my last deposition is where I changed my testimony. If it involved children I would agree with that.

Q. In this statement here, does it say the word children in the statement we violated?

A No, not specifically.

Q. Do you know of another generally accepted number in terms of how much diversion starts in the medicine cabinet at home? Have you seen another number that you would point us to as generally accepted?

A No. I'm just drawing on my experience working at DEA as a diversion investigator in both the criminal and the administrative cases, I believe that that's too high of a percent.

Q. That's experience solely in Detroit, correct?

A Yes, sir. And in reviewing cases and documents and stuff nationwide, for instance, the Florida situation, South Ohio, some involvements in other areas, Toledo, not specifically to Detroit, my experience isn't there. It just encompasses my time as a diversion investigator reading case studies and other cases and analysis. So that's where I draw.

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Just based on my experience and some of the knowledge while I was working.

Q. Your experience doesn't include working in Nassau County or Suffolk County or New York State, correct?

A It does not.

Q. In terms of coming up with a different number, you can't give me a specific different estimate, you just believe this number is too high, correct?

A For that specific statement I do.

Q. But you don't have a different number for us; do you?

A I do not. I do not.

Q. In terms of this specific statement, you haven't done any research or studies or read any periodicals about it, correct?

A Again, I answered that previously. It's all based on my experience and documents and cases and my exposure to the opioid epidemic. I have no exact percent that I would adjust it to.

Q. Come back to my question, sir.

Would it be true to say you haven't done any research or studies or read any periodicals

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about this number; would that be true?

A 70 to 80 percent, no, sir, I have not.

Q. Let's go back to the image demonstrative Exhibit 3, please. This doesn't appear on the exhibit, but you recognize that the DEA, your former employer, the Drug Enforcement Administration, overseas this whole prescription drug opioid process?

A Yes. I was a part of the agency. That was my task or responsibilities as a diversion investigator. I agree that this all encompasses my previous employment.

Q. They license every healthcare professional who can write a prescription for a prescription opioid, right?

A Yes, sir.

Q. They license pharmacies that can dispense prescription opioids, right?

A Legitimately, yes, sir.

Q. No one lawfully can prescribe a prescription or dispense one without getting licensed by the DEA and then in periodic intervals having their license or registration reviewed, right?

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1 A Just with the added caveat that they
2
3 also must maintain a state license for that state
4 they practice in.

5 Q. I'm going to come to the State in a
6 minute. Let's just focus on the DEA first.

7 The DEA has to license every provider
8 and every pharmaceutical, correct?

9 A Right. I don't want to argue. Only if
10 they have a valid New York State license. They
11 cannot obtain a DEA license without it so.

12 Q. And in your estimation, the DEA has
13 licensed a good deal of the pill mill doctors in the
14 United States, correct?

15 A Well, if they're issuing prescriptions
16 with the DEA registration, that would be a true
17 statement.

18 Q. In fact, based on your experience, you
19 had said it would probably be greater than a
20 thousand pill mill doctors the DEA has licensed,
21 correct?

22 A Over the course of the opioid epidemic,
23 I would agree with that statement, sir.

24 Q. And correspondingly, you would agree
25 that there were probably over a thousand pill mill

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pharmacies that DEA licensed?

A I would not disagree with that statement. I don't have an exact number but...

Q. You're aware that they've been criticized for the manner in which they licensed pharmacies and doctors throughout the opioid crisis, correct?

A And the source of that criticism; do you have that?

Q. I'm just asking you, are you aware that there have been some studies and some criticisms over DEA contributing to the opioid crisis?

A I don't know if contributing, but I know there have been some criticism of the DEA, internal or government investigations, I'm aware of those, not the exact language.

Q. Let's go back to your testimony, sir, where I asked you that exact same question, page 177, deposition. Can we -- I think I got the wrong citation in my notes -- no, it's right. Can we show the bottom. I think the question starts at the bottom of the page.

Can we go back to 177. It says, Okay, understood, and then if we go to page 28, 178, it

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says, Let me show you my next exhibit.

I asked you about, are you aware that the DEA has been criticized for contributing to the opioid crisis?

Do you see that question I just asked you a few moments ago?

A I do.

Q. Do you see your answer was: Yes, sir. I realize that there have been some studies and some criticisms. Do you see your answer?

A I do, but I don't recall what the exhibit was or what the source of that questioning in my statement is. That's the issue I'm having.

Q. Was that truthful testimony at the time?

A I don't know until I see the document.

Q. Okay. You don't know whether you can stand behind that sworn testimony?

A No. I'm cautious to say that until I see the document. I mean, I'm not disagreeing that those were my words I spoke that day.

THE COURT: Time out. Is the exhibit available?

MR. SCHMIDT: Yes. And I'm about to show him, your Honor.

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THE COURT: Okay.

Q. Let me show you what I'll mark as Exhibit F, it's tab 15 in the binder. It's from the Office of the Inspector General of the United States Department of Justice.

You recognize they are a government watchdog, right?

A I do.

Q. They're a watchdog in the same agency, the Department of Justice, that the DEA is a part of, right?

A They are.

Q. And if you look at the bottom, this is from September 2019; do you see that?

A I see that.

Q. It's entitled: Review of the Drug Enforcement Administration's regulatory and enforcement actions to control the diversion of opioids; do you see that?

A Yes, sir.

MR. SCHMIDT: May I just ask if the folks in the courtroom have a copy of this?

MS. CONROY: Yes.

MR. SCHMIDT: Does your Honor have a

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copy?

THE COURT: Yes.

MR. SCHMIDT: Thank you, Miss Conroy;
thank you, your Honor.

Q. Let's look at page 15 of this report.

A 15.

Q. Do you see halfway down the page there's
a heading with the criticism pre-registration
investigations did not adequately vet applicants; do
you see that?

A I see where it says that.

Q. Look at the second sentence, it says,
The purpose of a pre-registration investigation is
to determine the fitness and suitability of the
applicant to engage in the activities for which
registration is requested and to ensure that the
applicant is familiar with its responsibilities to
prevent diversion; do you see that?

A I do.

Q. That absolutely applies to registration
of doctors and pharmacies, correct?

A Yes, sir.

Q. However, we found that DEA's
pre-registration process did not appropriately

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1
2 safeguard against diversion of pharmaceutical
3 opioids or any other drug, because DEA did not
4 conduct background checks on all new applicants and
5 it relied instead on the good faith of applicants to
6 disclose relevant information, even in cases in
7 which the applicant had previously engaged in
8 criminal activity; do you see that?

9 A I do.

10 Q. You're familiar with this criticism of
11 DEA not carrying out its licensing responsibilities
12 correctly?

13 A I do. I remember my deposition. I
14 think I disagreed with that statement. We had a
15 discussion about it.

16 Q. Okay. And just so we're clear which
17 type of registrant we're talking about here, if you
18 look down in the next paragraph, please, it
19 distinguishes between type A and type B registrant.

20 Why don't we pull out that paragraph and
21 then we can continue over to the next page.

22 Are you familiar with that distinction
23 between type A and type B registrant?

24 A Yes, sir, I am.

25 Q. B registrant, do you see in the first

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sentence includes manufacturers, distributors and other entities?

A I do.

Q. According to the Associate Section Chief of the DEA's regulatory section, this is the first language in the paragraph, DEA conducts pre-registration inspections only on type B registrants, correct?

A Not totally accurate.

Q. Well, let's just read it. Do you see where it says right at the beginning, According to the Associate Section Chief?

A I acknowledge that's what it says.

Q. That was my question. That's what it says?

A That's what this statement says, yes, sir.

Q. It goes on to say in language that carries over to the next page, type A registrant, which includes physicians, dentists, pharmacists, are rarely required to undergo a pre-registration investigation; do you see that?

A I see what that document says, yes.

Q. That's the point where this report is

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being critical of DEA, correct?

A Yes.

Q. Are you aware that DEA has been criticized by setting quotas for prescription opioids too high?

A Generally, yes. I don't know the specific document, but I believe there is some criticism about their handling of the quotas.

Q. Do you agree with that?

A I don't remember the exact criticism. I'm not sure that I have enough experience or knowledge of the quota system being able to participate in to make a comment on that. Just general positions based on, you know, the level of my employment.

Q. You understand that the DEA every year sets to the pill the amount of prescription opioids that can be manufactured in the United States based on a judgment of medical and other needs?

A I understand the process, yes, sir.

Q. Now, you -- I want to come back to that topic. You said, in addition to what we've been talking about, the DEA and what the DEA does in terms of licensing, the State of New York, your

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client, also has to license every prescriber and every pharmacy and pharmacist in the State of New York, correct?

A Yes, sir.

Q. Both the DEA and the State of New York have the independent ability to keep a pharmacy from issuing prescription opioids or a doctor from writing prescriptions for prescription opioids, correct?

A I agree with that statement.

Q. Manufacturers, distributors and pharmacies can't keep doctors from writing prescriptions for prescription opioids, they don't have that same power, correct?

A Provide me the list again, I'm sorry.

Q. Manufacturers, distributors and pharmacies don't have the same power that the DEA in the State of New York has to keep a doctor or a healthcare professional from writing prescriptions for prescription opioids; they can choose not to fill it, but they can't stop the doctor from writing it and getting it filled somewhere else in the way that the State or the DEA can, correct?

A I agree with that statement.

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Q. Manufacturers and distributors don't have the same power that New York or the DEA has to shut down illegal pharmacies, correct? They can stop supplying them, but they can't shut them down the way New York or the DEA can?

A They have no state or federal administrative authority, I agree.

Q. Your report does not address and your opinions do not address the causal role of the DEA in the opioid crisis, including up to this point the criticism we talked about or the causal role in the State of New York opioid crisis, correct?

A It does not. I was not requested by the Plaintiffs' attorneys to formulate an opinion on that or opine on that.

Q. The Plaintiffs' lawyers for the State of New York did not ask you to give an opinion on whether the State of New York caused the opioid crisis?

A No, they did not.

Q. Okay. Somehow I'm not surprised.

Let me ask you a few questions about manufacturers.

Manufacturers produce prescription

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drugs, right?

A Yes, sir.

Q. They cannot sell prescription opioids or make them unless they are licensed by both the DEA and the State, right?

A That's an accurate statement, yes, sir.

Q. They can only make as much as the DEA allows through its quota, correct?

A Yes, sir.

Q. Are you aware of any instance --

A Of certain drugs, sir.

Q. Prescription opioids?

A Yes, sir.

Q. Okay. And I should be precise, but thank you for pointing that out, because I'm just going to focus on prescription opioids.

There's no instance, you're aware of, where a manufacturer who is a Defendant in this case sold a controlled substance to a distributor in New York or a pharmacy in New York that did not have a license in both the State of New York and the DEA, correct?

A I agree with that statement, sir.

Q. On the pharmacy side, pharmacies order

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1 directly from distributors and dispenses them to the
2 patients, correct?

3
4 A Yes, sir.

5 Q. You understand that there's a difference
6 between a lot of the independent pharmacies you talk
7 about in your report and the four chain pharmacies
8 that are Defendants in this case?

9 A Differences in -- can you elaborate on
10 that?

11 Q. Sure. One difference is that the four
12 Defendants who are pharmacies in this case, the
13 chain pharmacy Defendants, they sometimes self-
14 distribute, whether they distribute prescription
15 opioids but only to their own stores, correct?

16 A I would agree with that. I just wanted
17 a clarification because in the end they're both
18 retail pharmacies. It's just the manner they
19 acquire their drugs.

20 Q. Independent pharmacies don't self-
21 distribute, correct?

22 A No, not that I'm aware of.

23 Q. When it comes to independent pharmacies,
24 even the ones you talk about in your report, am I
25 correct that you don't address their role in causing

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the opioid crises in your report?

A That's a correct statement. I wasn't asked to investigate that matter or opine on it.

Q. You're not giving opinions on that, correct?

A I am not.

Q. A distributor -- let's turn to distributors now -- cannot participate in the system without them being registered by the DEA or by the State, correct?

A That's correct.

Q. They can only sell prescription opioids or provide prescription opioids to pharmacies that have a DEA and a State registration, correct?

A Yes. Just a little clarification on that. I believe it's a requirement in some states that they may have to have a state license for those states they distribute to also, but just so the record is clear, I don't want that I didn't know that or say that.

Q. Okay. You're not aware of Cardinal or McKesson or ABDC of selling controlled substances to a pharmacy that was not licensed by the DEA or the State of New York, correct?

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1
2 A I'm not aware of it, but just so it's
3 clear, my testimony is that I'm not saying it didn't
4 occur.

5 Q. You couldn't point us to an instance
6 where it would have occurred, particularly in New
7 York, right?

8 A I could not.

9 Q. I want to ask you three sets of
10 questions about distributors and then I'll move on
11 to my next topic.

12 First, are you aware of how many total
13 distributors are in the United States?

14 A Since I've left my employment, no, I'm
15 not.

16 Q. Are you aware that, ballpark, it's
17 hundreds and hundreds?

18 A I wouldn't disagree with hundreds and
19 hundreds, yes, sir.

20 Q. You only focus on three in your report,
21 correct, the largest three, to be fair, but three,
22 correct?

23 A Say that again, I'm sorry.

24 Q. You only focus on three distributors in
25 your report, correct?

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A No. I think there are other distributors in my report.

Q. Which other distributors do you give opinions about that are not also chain pharmacies?

A Oh, the other distributors would be chain pharmacies. I didn't realize you qualified that question.

Q. Yeah, and I just did qualify it, to be fair to you.

The only independent distributors you talk about in your report are McKesson, Cardinal and ABDC?

A I agree with that. The other distributors are really chain distributors.

Q. Are you aware there are other distributors that you don't talk about that are listed in Defense Exhibit B of the Complaint that tracks through to your report; are you aware of that?

A Yeah, I believe so. Yes, sir.

Q. For example, do you know who Rochester Drug is?

A I do.

Q. Do you know that there is currently

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criminal activity involved with Rochester Drug?

A Yes, I do.

Q. Do you know if their standards are better or worse than McKesson, ABDC or Cardinal?

A I didn't review anything for Rochester Drug.

Q. Do you know if they or any of the other hundreds of distributors supplied any of the pharmacies you talk about in your report as to McKesson, Cardinal and ABDC?

A Just generally reply to that in reviewing due diligence records. I did see that there were some instances where Rochester Drug or RDC was a supplier or secondary supplier on some of the pharmacies.

Q. Did up undertake any effort to ascertain the role of RDC versus the alleged role of McKesson, Cardinal or ABDC?

A No, sir.

Q. Do you know if Rochester Drug or any other distributor that you did not review is responsible for more or less alleged diversion than the Defendants in this case?

A Well, I can answer that just based on my

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2 knowledge of the industry, but I don't have a

3 specific evaluation to give you numbers or just

4 say --

5 MR. SCHMIDT: I think we lost Mr.
6 Rafalski for a moment. I take it you all can
7 still hear me.

8 Mr. Rafalski, can you hear us?

9 IT TECHNICIAN: It's on his end.

10 THE COURT: Mr. Rafalski?

11 MS. CONROY: We'll try to reach them,
12 your Honor, on the phone to see if we can
13 reach them on the phone.

14 IT TECHNICIAN: We just removed him from
15 the meeting so if he can rejoin.

16 THE COURT: Mr. Schmidt, what kind of
17 mic are you using?

18 MR. SCHMIDT: I'm in a room with one of
19 those goofy little cameras on top of a TV,
20 and I think the camera has the mic. Is it
21 not coming through well?

22 THE COURT: It's coming through. It's
23 like I'm listening to Led Zeppelin all
24 afternoon. It's kind of loud.

25 MS. CONROY: Don't sing. Don't sing,

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Mr. Schmidt.

MR. SCHMIDT: I will not. I will be held in contempt if I did...

And I've been trying to speak up, your Honor, because I was worried about being heard, so I'm trying to be a little more muted.

THE COURT: Any luck?

MS. LICARDI: He's not in yet.

THE COURT: Is there some kind of process we should be following now?

MS. LICARDI: I see him asking to be let in, and I let him in.

THE COURT: Welcome back.

THE WITNESS: Thank you, your Honor.

THE COURT: Stephanie, I believe there's an open question; am I correct?

(WHEREUPON, the requested portion was read by the reporter.)

THE COURT: Mr. Schmidt, do it again, please.

Q. Did you try to come up with any kind of calculation of the relative role of Rochester Drug or any of the other hundreds of distributors versus

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McKesson, versus ABDC, versus Cardinal in terms of how effective the controls were comparatively or anything like that?

A No, sir.

Q. Second set of questions on distributors.

Do you agree that distributors provide prescription opioids to pharmacies, correct?

A Yes, sir. That would be one of the registrants they would distribute to not exclusively.

Q. Distributors and manufacturers don't check the prescriptions that patients bring into the pharmacy, that's what the pharmacy does, correct?

A They don't review it the same way a pharmacist does, if that's what you're asking. I agree with that.

Q. They don't fill the prescriptions brought to them, that's what a pharmacy does, correct?

A Yes, sir.

Q. In your opinion where it focuses on distributors is focused on obligations that distributors have related to pharmacies, such as walking orders, conspicuous orders, conducting

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diligence, correct?

A That's the extent of my opinion, yes, sir.

Q. Do you remember me asking you at a deposition about whether independent pharmacies that acted improperly caused the opioid crisis?

A I don't recall that question.

Q. Do you recall giving the answer that, I don't know if I would say caused, they're so far down the line?

A I generally remember. I think I might have said contributed, but not caused.

Q. And just so we're not talking in the abstract, let's just put up the transcripts, if we could, tab 2, page 167, 168. 167, line 23, down through 168, line 12. I think in the prior answer you talked about contributed.

Why don't we go back up to the question and answer just for completeness.

I asked you -- well, let me ask, were pharmacies, independent pharmacies that acted improperly, did they help in terms of dispensing prescription opioids, and you said just now, Mr. Rafalski, you said the cause causes some concern;

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again, I think they contributed.

And then here's the part I want to ask you about. I asked, You contributed, and you said, I don't think I would stake odds. They are so far down the line.

And then if you want to just read the rest of the answer to yourself, I'm going to ask about that "so far down the line" statement.

A I read my response.

Q. Okay. Do you stand behind that testimony that you don't know if you would say cause as to independent pharmacies, because they are so far down the line?

A I probably wouldn't state that today. I would probably -- I think I maybe contradict myself a little bit later on in this statement or it's probably not as precise as I'd like, that they're so far down the line. They're obviously within that close system. They're not at the level of the manufacturers or the distributors, and I think that's my reference, too, but that's probably not the best language, but I acknowledge I said that.

Q. Okay.

THE COURT: Excuse me. Going forward,

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1 let's do it right. Anytime you go into a
2 transcript, a deposition, you'll notify the
3 Court the page and the lines, and you'll
4 phrase your question this way: Do you recall
5 being asked this question and giving this
6 answer and give a complete answer, and then
7 go from there.
8

9 MR. SCHMIDT: Okay. Understood, your
10 Honor.

11 Q. Is there any contribution you believe
12 that you talk about in your report that ABDC,
13 Cardinal or McKesson made to the opioid crisis that
14 did not involve providing prescription opioids to
15 pharmacies in New York? Anything you talk about in
16 your report or in your opinions, other than
17 providing prescription opioids to pharmacies?

18 A Well, the distribution aspect of this,
19 the only thing that I was asked to investigate and
20 formulate a report on, if there was some -- if there
21 was some sales activity or some other activity that
22 contributed to some elicit activity, I wasn't tasked
23 with researching that aspect of it. So kind of
24 that's a long answer but I -- go ahead, I'm sorry.

25 Q. Let me see if I can summarize it.

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You focused only on distribution of pharmacies, correct?

A Yes, sir.

Q. Let me turn to my third point on distributor. Remember when I was asking you as contrasting the power that New York State or the DEA has to shut down a pharmacy versus the power that -- the absence of that power that distributors or manufacturers have; do you remember me asking you those questions?

A I do.

Q. If a distributor imposes some kind of limit or cuts off a customer a pharmacy will go find some other distributor, correct?

A There's a possibility.

Q. Well, generally speaking, that's true, correct?

A Well, to merely just cut them off or stop shipping to them, I guess if they fail to report a suspicious store, and they fail to notify authorities, if the pharmacy wants to stay in business they would have to go seek out another distributor to continue to receive drugs. So, in general, I agree with that statement.

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1 Q. Are you aware of the number of instances
2 from this case where the distributor Defendants in
3 this case reported a pharmacy to the DEA or to New
4 York State and no action was taken, and the pharmacy
5 remains open until this date?
6

7 A Yeah, I believe we covered that on my
8 first deposition. I'm aware of that, yes, sir.

9 Q. Do you know how many instances of that
10 occurred where a distributor reported a pharmacy as
11 suspicious, and the state or the DEA did not act on
12 them, and they remain open until this day?

13 A I did not research that or investigate
14 that and was not required to put that into my
15 report. No, sir, I do not know.

16 Q. You don't know if that happened a dozen
17 times, 100 times, more or less?

18 A I have no idea.

19 Q. Have you ever heard of a pharmacy that
20 was cut -- I'm sorry -- have you ever heard of a
21 doctor or a healthcare professional who was
22 inappropriately writing opioid prescriptions and who
23 was stopped because a distributor cut off a specific
24 pharmacy?

25 A Stopped from writing prescriptions?

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Q. Correct.

A If that's a hypothetical question, if that doctor's conduct was so bad that there was only one pharmacy that was filling his prescriptions, that's a possibility. It's a hypothetical. Go ahead.

Q. Did you see any instance of that in your review of New York documents regarding New York pharmacies and New York doctors where cutting off a pharmacy put a doctor who was acting improperly out of business?

A No, sir.

Q. Sir, I just want to wrap this line of questions up.

THE COURT: We're backing up to 4:30. How much more -- how much longer do you think you need on your portion of this examination?

MR. SCHMIDT: I'm going to be done with this section in two minutes. I have probably another hour or hour-and-a-half after that.

THE COURT: So use the two minutes to exhaust this line and then we'll break.

MR. SCHMIDT: Okay. Thank you, your Honor.

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1 Q. Just to wrap up, Mr. Rafalski, as I
2 understand it, I asked you about all these different
3 entities in the prescription opioid process, patient
4 distributors, pill mill doctors, medical profession
5 generally, your mission in your report was not to
6 analyze all the causes in the opioid crisis,
7 correct?
8

9 A Yes, correct. When I was hired and I
10 had meetings in regards to the report, the
11 investigation and report, I was given the specific
12 parameters of what my report would contain and where
13 I would do my research.

14 Q. Your process, your methodology in your
15 report was meant to consider looking at all factors
16 that may have contributed to the opioid crisis, how
17 much responsibility different individual entities or
18 people bare, correct?

19 A That's correct.

20 Q. You haven't purported to go through all
21 the potential factors that played in the opioid
22 crisis and say these are the ones that are the most
23 important factors, these are the ones that are minor
24 factors, correct?

25 A Yes. My paper does not look at the

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totality of the opioid crisis and all the participants or factors. I agree with that statement.

Q. Including identifying who's a substantial factor, who's an important factor, correct?

A I don't agree with that. I think my report identifies some substantial factors, but it does not encompass all of the people that participate in the opioid epidemic.

Q. Or even all of the substantial factors, right?

A I would agree there is probably some outside of the area that I covered.

MR. SCHMIDT: This is probably a good place to stop, your Honor, if that's okay with the Court.

THE COURT: Okay. We'll recess till 9:45 tomorrow morning.

Am I to expect other defense lawyers examining this witness? There's correspondence that had gone back and forth suggesting that whenever an expert's opinion cross-divisions, so to speak, manufacturers,

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distributors and pharmacies, that the Defendants were seeking the right to have a separate counsel as to each category.

Is that out the window or is that still the menu?

MS. REISMAN: Your Honor, this is Sharyl Reisman on behalf of Walmart. I intend to ask very few questions, but I will have a few questions.

THE COURT: That's a yes?

MS. REISMAN: That's a yes.

MR. O'CONNOR: Speaking of manufacturers, we may have a few questions as well, but it will be very brief.

THE COURT: Okay.

MS. LEVY: Jennifer Levy. Your Honor, this is Miss Levy for the Allergan Defendants. Can I ask a question before we recess for the day about the remainder of the week?

MR. SHKOLNIK: That's why I was standing up, your Honor.

THE COURT: About the remainder of the what, the week?

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MS. LEVY: Yes, your Honor.

THE COURT: I have some letters on my desk. I had set forth a schedule in my last Short Form Order that talked about Mr. Rafalski today and tomorrow and Craig McCann on August 19th, and the letters deal with the continuation with the next witnesses, which is scheduled for Thursday and Friday of this week, to take them -- to kick them over into September. Is that what you're asking me about?

MS. LEVY: Yes, your Honor.

THE COURT: Speak your peace.

MS. LEVY: My question, your Honor, the Plaintiffs had requested that this witness be moved to September 11th. The defense does not disagree, but we wanted to make sure that your Honor had no problem with the agreed moving of the date for Lacey Keller to September 11th, and if a second day is needed, September the 14th.

THE COURT: We will be down the 20th through the 21st, correct?

MS. LEVY: That's correct, your Honor.

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THE COURT: Just out of curiosity,
what's the reason? I'm curious, what's the
reason?

MS. CONROY: Your Honor, Jane Conroy.
The reason we had initially done it was there
were questions about whether or not a live
examination would be possible, because Ms.
Keller is going to testify live. It may not
be that the Defendants wish to do that, but
the accommodation was originally made so that
someone could travel to New York with the
quarantine restrictions in order to examine
her. Then we changed the -- so we reached
out to the Defendants and, frankly, kind of
worked the schedule to make that happen. So
that's why this came about.

THE COURT: But we're still going to do
Dr. McCann, right?

MS. CONROY: Yes. Dr. Craig McCann is
scheduled for Wednesday.

THE COURT: So you want to move Lacey
Keller to September 11th and 12th, if
necessary?

MS. CONROY: That's right.

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That's a Friday. So then it would go --
she would be Monday, if necessary. If we
don't need that Monday, then our final
witness, Dr. Tomarken, would testify.

THE COURT: Sandy, first thing tomorrow
morning, let's see if we backed ourselves
into anything on September 11th. If we
haven't, we can accommodate you.

Okay, let's close the record.

* * *

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C E R T I F I C A T I O N

I, Stephanie Casagrande Hague, CSR, RPR,
an Official Court Reporter of the State of
New York, County of Suffolk, do hereby
certify that the above is a true and accurate
transcription of my stenographic notes taken
in the above-entitled action on this day;

Furthermore, photocopies made of this
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STEPHANIE CASAGRANDE HAGUE, CSR, RPR
Official Court Reporter

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